

# Setting Science-Based International Food Standards: Defining Dietary Fibre in the Codex Alimentarius Commission

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## Abstract

The thesis presents a sociological analysis of international food standard-setting in the Codex Alimentarius Commission (the Codex). The Codex is an intergovernmental organisation jointly administered by the UN Food and Agricultural Organisation and the World Health Organisation. The main activity of member governments who participate in the Codex is the negotiation of international food standards, which are referenced by World Trade Organisation agreements. Although international food standards are significant instruments which structure the agri-food system, little social science research has been conducted on the process by which such standards are set.

In order to develop an in-depth analysis of the science-based standard-setting process, the thesis analyses a case-study of the attempt to agree a definition of dietary fibre within the Codex. Agreeing a definition of dietary fibre was a protracted and contentious process within the Codex, with important implications for food product development and the creation of new markets. Methods used in the study included: observations of meetings, document analysis and thirty-two interviews with scientists, government delegates and food industry and consumer representatives. In this case-study, the concept of epistemic communities – defined by Haas (1992a: 3) as “...a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within the domain or issue-area” – was deemed to provide a weak explanation for the standard-setting process due to a failure to address the conditions giving rise to particular knowledge claims. Instead – and following critiques developed within the sociology of science and technology – the analysis suggests that international food standard-setting uses scientific knowledge claims, but cannot be said to be wholly based upon science because of the constitutive entanglement of science and politics. The thesis argues that the production of a definition for dietary fibre followed a methodology of standard-setting that required dietary fibre to become a ‘boundary object’ (Star and Griesemer, 1989) – an identifiable object around which conflicting groups can co-operate because the object possesses just enough ambiguity to allow for multiple interpretations.

The thesis concludes that, in this case-study, on-going scientific controversy does not prevent the agreement of a food standard – despite food standards being ‘science-based’ – if the standard in question can be negotiated as a boundary object. The thesis provides novel social scientific insights into a little studied, but increasingly significant, area of the agri-food system.

# Contents

Acknowledgements		i
Acronyms and Abbreviations		ii
List of Figures		iii
<b>Chapter One</b>	<b>Introduction</b>	<b>1</b>
	1.1 Research Aims	1
	1.2 Economic Globalisation, International Trade and Food	3
	1.3 Thesis Structure	11
<b>Chapter Two</b>	<b>Theorising International Agri-Food Regulation</b>	<b>15</b>
	2.1 Introduction	15
	2.2 The Concept of an Agri-Food System	15
	2.3 Expertise and International Regulation: The Role of Epistemic Communities	24
	2.4 Critiques of the Epistemic Communities Concept	30
	2.5 Science and Regulation: Alternative Approaches	36
	2.5.1 Boundary Work	36
	2.5.2 The Core-Set of Scientists	38
	2.5.3 Regulatory Cultures and Risk	40
	2.5.4 Regulatory Diffusion and Standard-Setting	45
	2.5.5 Constructing and Mediating Boundaries	52
	2.6 Conclusions	55
<b>Chapter Three</b>	<b>Producing the Case-Study</b>	<b>57</b>
	3.1 Introduction	57
	3.2 The Codex Alimentarius Commission as a Case-Study	58
	3.3 Methodology	69
	3.4 Introducing the Empirical Analysis	79
<b>Chapter Four</b>	<b>Dietary Fibre as Regulatory Dilemma</b>	<b>81</b>
	4.1 Introduction	81
	4.2 The Scope and Content of a Definition for Dietary Fibre	85
	4.3 In and Around the Nutrition Committee	94

	4.4 Making Comments in Codex	106
	4.5 Conclusions	109
<b>Chapter Five</b>	<b>The History of Dietary Fibre Science and Technology</b>	<b>113</b>
	5.1 Introduction	113
	5.2 Discovering Dietary Fibre	116
	5.3 Defining Dietary Fibre	121
	5.4 Disputing Dietary Fibre	127
	5.5 Conclusions	132
<b>Chapter Six</b>	<b>Knowledge Claims and the Definition of Dietary Fibre</b>	<b>134</b>
	6.1 Introduction	134
	6.2 Scientific Advice and the Definition of Dietary Fibre	134
	6.2.1 European Commission and Scientific Advice	136
	6.2.2 United Kingdom and Scientific Advice	142
	6.2.3 United States and Scientific Advice	145
	6.2.4 FAO/WHO and Scientific Advice	147
	6.3 Knowledge Claims and Scientific Techniques: Evidence and Analysis	151
	6.4 Conclusions	157
<b>Chapter Seven</b>	<b>Standard-Setting: Methodologies and Boundary Objects</b>	<b>159</b>
	7.1 Introduction	159
	7.2 Codex Standard-Setting as a Methodology	162
	7.3 Technical Controversies and Boundary Objects	170
	7.4 International Food Standards and Agri-Food Governance	180
<b>Chapter Eight</b>	<b>Conclusions and Future Research</b>	<b>185</b>
	8.1 Conclusions	185
	8.2 Future Research	192
<b>References</b>		<b>195</b>
<b>Appendices</b>		<b>213</b>



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## *Acronyms and Abbreviations*

The Codex:	Codex Alimentarius Commission (referring to the international organisation)
The Codex Commission:	Codex Alimentarius Commission (referring to the high-level committee of the Codex)
Codex Executive Committee:	Executive Committee of the Codex Alimentarius Commission
Codex Nutrition Committee:	Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses
Codex Principles Committee:	Codex Committee on General Principles
AACCI:	American Association of Cereal Chemists International
AAF:	European Starch Industry Association
ACNFP:	United Kingdom Scientific Advisory Committee on Novel Foods and Processes
AFSSA:	Agence Francaise de la Securite Sanitaire des Aliments
AOAC:	Association of Analytical Communities
CAP:	Common Agricultural Policy of the European Community
CEC:	Commission of the European Community (applied to official documents only, otherwise reference is made to the European Commission)
CFCs:	Chlorofluorocarbons
CIAA:	Confederation of Food and Drink Industries of the EEC
DoH:	United Kingdom Department of Health
DP:	Degree of Polymerisation
EU:	European Union
EFSA:	European Food Safety Authority
FAO:	Food and Agricultural Organisation of the United Nations
FDA:	United States Food and Drug Administration

## *Acronyms and Abbreviations (continued)*

FSA:	United Kingdom Food Standards Agency
GATT:	General Agreement on Tariffs and Trade
HACCP:	Hazard Analysis Critical Control Point System
IADSA:	International Alliance of Dietary / Food Supplement Associations
IBFAN:	International Baby Food Action Network
IBRD:	International Bank for Reconstruction and Development
ICGMA:	International Council of Grocery Manufacturers Associations
IDF:	International Dairy Federation
ILSI:	International Life Sciences Institute
IMF:	International Monetary Fund
IoM:	Institute of Medicine of the National Academies
ISDI:	International Special Dietary Foods Industries
ITO:	International Trade Organisation
IWC:	International Whaling Commission
IUNS:	International Union of Nutritional Sciences
MAFF:	United Kingdom Ministry of Agriculture, Fisheries and Food
MNC:	Multi-National Company
NAFTA:	North American Free Trade Agreements
NSP:	Non-Starch Polysaccharides
OECD:	Organisation for Economic Cooperation and Development
PTF:	Provision Trade Federation
SACN:	United Kingdom Scientific Advisory Committee on Nutrition
SPS:	Agreement on Sanitary and Phytosanitary Measures
TBT:	Agreement on Technical Barriers to Trade
TDF:	Total Dietary Fibre
UK:	United Kingdom
US:	United States of America
USDA:	United States Department of Agriculture
WHO:	World Health Organisation of the United Nations
WTO:	World Trade Organisation

## *List of Figures*

- Figure 2.1: The contemporary agri-food system (p. 17)*
- Figure 2.2: Comparison of three epistemic communities and their constituent elements (p. 26)*
- Figure 2.3: Dimensions of three modes of international standardisation (p. 49)*
- Figure 3.1: Basic organisational structure of the Codex (p. 61)*
- Figure 3.2: Meeting of the Codex Alimentarius Commission in 2007 (p. 62)*
- Figure 3.3: Codex pre-2003 risk analysis framework (p. 65)*
- Figure 3.4: Codex post-2003 risk analysis framework (p. 66)*
- Figure 4.1: Time line of main decision-making events (p. 84)*
- Figure 4.2: Draft Table of Conditions (p. 89)*
- Figure 4.3: The Codex Nutrition Committee breaks for coffee (p. 99)*
- Figure 4.4: The use of a word processor to produce Codex standards (p. 102)*
- Figure 5.1: Basic human digestive system (p. 115)*
- Figure 5.2: Proposed relationship between cancer and processed foods (p. 118)*
- Figure 5.3: The demarcation of the dietary fibre concept (p. 125)*
- Figure 7.1: Adopted Codex definition of dietary fibre (p. 175)*

# Chapter One – Introduction

## 1.1 Research Aims

The thesis is concerned with the operation of international standard-setting for traded food products within the Codex Alimentarius Commission (the Codex). The Codex is an intergovernmental organisation jointly administered by the UN Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO). Member governments of the Codex negotiate and agree international food standards. According to Article 1 of the Statutes of the Codex (Codex, 2008e), the Codex is responsible for matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, which aims to: protect the health of consumers and ensuring fair practices in the food trade and promote co-ordination of all food standards work undertaken by international governmental and non-governmental organisations.

With the establishment of the World Trade Organisation (WTO) in 1994, new international agreements came into force with consequences for the Codex. The finalisation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT)<sup>1</sup> confers a new status upon the standards agreed in the Codex by linking them to the international trading system. The standards agreed in the Codex are not mandatory; they do not provide a substitute or alternative to national legislation. However, as Codex standards are now located within the international trade system there is an expectation that member governments of the WTO will use the standards agreed in the Codex as a basis for national food laws. As a result, the standard-setting process within the Codex involves political, legal, economic, scientific and public health considerations.

Despite the significance of these developments for the governance of the agri-food system, they have received relatively little attention from social scientists. Frequently accounts of the global agri-food system have focused upon the outcomes of regulatory reforms, but have seldom addressed the process of producing regulatory reform. As argued in Chapter Two of the thesis, further understanding is required of the production

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<sup>1</sup> Both the SPS and TBT agreements will be discussed in more detail in the following section.

of seemingly technical instruments such as international food standards, given their potential significance. An objective of this research is to raise the profile of this important area of international decision-making among social scientists.

The aims of the research are:

- To produce a sociological analysis of the standard-setting processes for food products within the Codex Alimentarius Commission using the contention over the definition of dietary fibre as a case-study.
- To explore the broader implications of these processes for the governance of the agri-food system.
- To draw conclusions about the operation of the Codex Alimentarius Commission and to highlight areas for future research on food standards and regulation.

In order to fulfil these aims, the thesis addresses a number of questions detailed below:

- How are international food standards set?
  - How can the standard-setting process be understood from a sociological perspective?
- Are international food standards set on the basis of science?
  - Is there a scientific basis for the standard-setting process?
- What is the relationship between scientific advice and standard-setting?
  - How is scientific advice produced and what impact does it have upon the production of international food standards?
- How does the institutional organisation of standard-setting influence the standard-setting process?
  - In what ways do the procedures and frameworks of the Codex guide standard setting?

- How is consensus established amongst member governments in order to agree international food standards?
  - What maintains the coherence and stability of the standard-setting process?
- How are the material components of food products conceptualised within the standard-setting process?
  - What impact does the chemical and biological composition of food have upon the process of setting international food standards?
- What are the implications of this analysis of international food standard-setting for understanding the governance of the agri-food system?
  - How should the governance of the agri-food system be conceptualised and analysed?

In order to address these questions, the thesis focuses upon an analysis of the agreement of a definition of dietary fibre within the Codex. The process of agreeing a definition of dietary fibre in the Codex has proved contentious, with some food companies eager to make claims for food products on the basis of a revised definition. As a case-study, the negotiation of an international definition for dietary fibre provides an important lens on the specifics of standard-setting and the broader implications of international standards.

By way of introduction to the study, the following section details how the standard-setting activities of the Codex are positioned within a broader trend towards economic globalisation and the expansion of international trade regulation into new policy domains.

## 1.2 Economic Globalisation, International Trade and Food

In the 21<sup>st</sup> century food products are traded across nations at historically unprecedented levels. Between 1980 and 2005 the total value of international exports in food products increased from US\$224 billion to US\$683 billion (WTO, 2007). Bulk food commodities such as sugar, tea, wheat, maize and meats have long been traded and in

recent decades this trade has increased.<sup>2</sup> Allied to this has been a growth in the number of nations participating in food trading activity and an increase in the array of traded food products. As a result, the volume of food products traded has increased, the variety of food products traded has increased and the number of firms importing and exporting products has increased and from a greater range of countries. The rising volume of trade in food commodities and products between nations is considered by some to be essential for ensuring food security. In 2002, Miguel Rodríguez Mendoza, then Deputy Director-General of World Trade Organisation, suggested that national food security strategies should have a significant international trade component rather than aiming for national self-sufficiency (WTO, 2002). Such an approach to food security has provoked resistance from those opposed to the continuing growth of an international trade orientation in food production (see, for instance, Windfuhr and Jonsen, 2005).

The increase in international trade in food products has emerged within a general movement towards economic globalisation. According to Held (2004) economic globalisation is a form of global economic integration<sup>3</sup> comprising three domains of activity: production, finance and trade. Productive activity has become globalised mainly through the rise of multinational corporations (MNCs) which oversee networks of production across countries. International financial activity has become focused upon speculative hedging against currency valuations (Strange, 1997).<sup>4</sup> The third domain in Held's discussion of economic globalisation is that of international trade in goods and services. International trade links production systems across nations. Whereas international trade may have once been conducted largely independently of national production, trade orientation is now an important feature of national production. As a result, systems for production have not only been reconfigured around the MNC, but national production is also adjusting to an international trade imperative.

International trade has also become a prominent driver in shaping international political institutions. Kelly and Grant (2005) suggest that concerns over international trade have

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<sup>2</sup> By way of example, the total worldwide quantity of exported raw sugar rose from 28.3m tonnes in 1985 to 53.0m tonnes in 2006, while wheat exports rose from 96.0m tonnes in 1985 to 126.2 tonnes in 2006 (FAO, 2009).

<sup>3</sup> Held (2004) notes that the degree of integration is open to dispute. Le Grain (2002: 110) has commented that "...the world economy is still more of a ragged patchwork than a seamless web."

<sup>4</sup> With (as has been recently demonstrated) potentially far-reaching (and even disastrous) consequences for national economies.



resulted in a new trade politics, with an increasing number of policy issues brought under the trade banner. The rise of a trade politics poses problems for international political architecture. According to Stiglitz (2006: 21):

In effect economic globalisation has outpaced political globalisation. We have a chaotic, uncoordinated system of global governance without global government, an array of institutions and agreements dealing with a series of problems, from global warming to international trade and capital flows.

The chaotic system suggested by Stiglitz (2006) is driven by economic globalisation. Viewed from this perspective, economic globalisation is a driver of uncertainty over the appropriate forms of global governance. Notions of global governance – and the questions it deals with – have in turn been triggered by the processes of economic globalisation.

As far as the rise of international trade as an activity and as a broad policy domain is concerned, questions of governance have been closely related to the creation of the WTO. However, the WTO, formed in 1986, has its origins in an earlier period in which economic globalisation was a pressing concern. At the Bretton Woods meetings held in 1944<sup>5</sup>, three organisations were proposed in order to assist and structure economic relationships between states: the International Monetary Fund (IMF), the International Bank for Reconstruction and Development (IBRD) and the International Trade Organisation (ITO). The IMF was intended to regulate the international financial system through control of exchange rates and balances of payment. The IBRD would provide loans to governments through the issuing of bonds and was primarily intended to help finance reconstruction work in Europe and Japan. It was envisaged that the ITO would govern the rules and regulations for liberalised trade. However, while the IMF and the IBRD<sup>6</sup> were established, only one element of the ITO emerged – the General Agreement on Tariffs and Trade (GATT). Scammell (1992) argues that the failure of the ITO was a result of disagreement over the method of reducing tariffs between the United States of America (US) and the United Kingdom (UK). The UK wished to retain the ‘Imperial Preference’ tariff system – a system of free trade agreements within the British Commonwealth – while the US sought non-discrimination in trade. Despite

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<sup>5</sup> The Bretton Woods meetings were held between Allied nations during the Second World War in order to plan the post-war international economic system.

<sup>6</sup> The IBRD is one of two programmes which comprise the World Bank.

such disagreements, the GATT developed through a series of negotiating rounds, the first being the Geneva Round of 1947, and the most recent the Doha 'Development' Round, formally suspended in July 2008.

The initial objectives of the GATT were to instigate:

...reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce...

(GATT, 1947)

While the articles of the 1947 GATT were relevant to agriculture and food, two sector-specific exceptions allowed the continuation of quantitative import restrictions and export subsidies on agricultural products. Among many developed nations protectionist agricultural policies were entrenched, and in 1958 the Common Agricultural Policy (CAP) was adopted by some European states. Agricultural trade became a central focus of the Dillon Round (1960-61) and the Kennedy Round (1963-1967), with the limited reduction of some tariffs being agreed in the latter negotiations. In subsequent decades, crises in agricultural policy focused attention upon scarcity and supply rather than trade liberalisation. It was not until the launch of the Uruguay Round (1986-1994) that international agricultural trade liberalisation began apace. The round also – finally – gave rise to an international organisation dedicated to administering the rules of world trade: the WTO.

During the Uruguay Round negotiations, agriculture and food became progressively incorporated into the international trading system. The Agreement on Agriculture (AoA), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) were important elements of this new international framework for trade in agricultural commodities and food products. The AoA was agreed with the intention of reducing domestic state support for agriculture, improving market access for agricultural imports and reducing subsidies provided to agricultural exports. The TRIPS agreement deals with the protection of intellectual property, including biological and microbiological processes for the

production of plants or animals and plant varieties. The most important Uruguay Round agreements for the concerns of this thesis are the SPS and TBT agreements.

With the finalisation of the agreements administered by the WTO, international trade regulation has become an important site of agri-food governance. Food production subsidies, food import tariffs, food export subsidies, food safety, food quality and food provenance are all covered by this suite of international agreements. Trade regulations have potentially far-reaching effects on the structuring of the agri-food system across member countries and regions. The dynamic of these agreements is oriented around the reduction and eventual removal of all 'barriers' to trade, often referred to as a trade liberalisation imperative. The movement towards a more liberalised trade system in which barriers are steadily reduced has been placed within a broader political project termed neo-liberalism or economic liberalism, defined by Carrier (1998) as a belief in a distinctly 'economic' realm of life determined by the maximisation of self-interest. Cockett (1995) chronicles the rise of economic liberalism as an intellectual and political project from 1931 to 1983 and suggests that "...the internationalisation of the work of the British 'think-tanks' was one of the most extraordinary features of economic liberalism as it developed in the 1980s." (Cockett, 1995: 306). The account offered by Cockett (1995) details infiltration by the intellectual project of economic liberalism into the political activities of national governments. In the international arena, the 'Washington Consensus' was taken as the political expression of economic liberalism and was manifest in the international development approaches of the IMF, World Bank and US Treasury. Early attempts to implement this programme of political economy centred upon reforms in Latin America and led John Williamson to coin the term "Washington Consensus" owing to the location of these institutions (Williamson, 1990). According to Serra *et al* (2008) the approach was focused upon a form of market fundamentalism which asserted that privatisation, liberalisation and price stability were necessary conditions for development. It is this era of economic liberalism in which the architecture of the international trade system should be situated.

The liberalisation of international trade – often termed a 'free-trade' agenda<sup>7</sup> – is the primary aim of the WTO and therefore member governments of the WTO must deal

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<sup>7</sup> Trentmann (2007) suggests that free-trade has long been a contested notion with multiple moral implications.

with this regulatory pressure, underpinned by a dispute settlement procedure which allows member governments to challenge the regulatory decisions of other member governments. So-called tariff barriers to trade – such as import tariffs, export subsidies and domestic support payments – have been reduced across most member nations in recent years, following the prescriptions of the WTO Agreement on Agriculture. Despite this, large differences in agricultural product tariffs between many Organisation for Economic Cooperation and Development (OECD) countries and developing countries can still be observed, although some developed countries still maintain tariffs on certain products<sup>8</sup>. Nevertheless, there has been a general movement towards a reduction of import tariffs and support to domestic exporters, particularly amongst developed countries<sup>9</sup>. As a result, increasing attention is being paid to so-called ‘non-trade barriers’ or ‘non-trade concerns’.

According to Vogel (1995) non-tariffs barriers are affecting an increasing percentage of food imports worldwide. Non-tariff barriers are many and various, depending upon the scope of definition and can include national import control systems and support payments for rural development activities, such those promoted in the CAP. They also include technical barriers to trade. Within the category of non-trade concerns, the term technical barriers to trade is applied to regulation in the form of technical standards and guidelines. It should be noted that this term does carry an assertion about the merits of non-trade concerns as barriers, in that they may viewed not as barriers but as essential to the protection of public health. Technical barriers to trade in food are particularly fraught with tensions, as Stiglitz (2006: 94) suggests:

Of all the non-tariff barriers, this is the most difficult to deal with. Governments have a right – and an obligation – to protect their citizens, and distinguishing between protectionist uses and legitimate standards is not easy. Some have called for the use of ‘scientific’ standards, but it is not even clear what should be acceptable levels of tolerance of risk.

As a result of the rising contention over technical barriers to trade, international food standards have assumed a heightened significance. Such non-trade concerns are

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<sup>8</sup> For instance, in 2006 the average final bound duty on animal products was 1.6% in Australia, 2.5% in the United States, 26.7% in the EU, 33.2% in Canada, 34.4% in Malaysia, 80% in Cameroon and 167.5% in Switzerland (WTO, 2006).

<sup>9</sup> However, the notable persistence of some production-oriented domestic support payments in the EU (through the Common Agriculture Policy (CAP)) and US (through the Farm Bill) have attracted criticism and have been cited as a cause of the ‘collapse’ of the Doha Round of trade negotiations in July 2008.

increasingly viewed as major elements of trade regulation and comprise those mechanisms of trade regulation which are not applied directly to traded goods. The issues dealt with by the SPS and TBT agreements are non-trade concerns and use science as a basis for decision-making. It is an aim of this thesis to analyse how science is used in setting the standards referenced by such agreements.

The SPS and TBT agreements provide a framework within which certain non-tariff barriers to trade can be addressed under the trade liberalisation imperative of the WTO. The SPS agreement deals with issues pertaining to the protection of human, animal and plant health in international trade. According to Zarrilli and Musselli (2004: 219):

The main goal of the SPS agreement is to prevent SPS measures from unnecessary negative effects on international trade and from being misused for protectionist purposes. However, the agreement fully recognises the legitimate interest of countries in setting up rules to protect food safety and animal and plant health, and in fact allows countries to give these objectives priority over trade, provided there is a demonstrable scientific basis for their food safety and health requirements.

Therefore, the SPS agreement gives a context for the agreement of SPS measures; the rules used by countries to protect against unsafe food, animal and plant diseases and alike.

The TBT agreement deals with technical regulations and standards relating to product specification and methods for assessing conformity to these specifications. As far as food is concerned, Hobbs (2001: 276) suggests that the TBT agreement is, relative to the SPS agreement, a “weaker arbiter of international trade disputes, because it deals with issues of packaging and labelling rather than the actual safety of the product; hence scientific principles may not be appropriate.” In this context member governments of the WTO have brought trade disputes to the dispute settlement mechanism under the stipulations of the TBT agreement. For instance, in 2001, Peru began a process of consultation with the EU over a European Commission Directive restricting the species of fish which could be classified and marketed as sardines. In this case, the naming criteria for sardines in the Directive departed from those set out in the Codex. The Codex standard detailed a number of species which could be labelled as sardines with a geographical qualifier, and so the Peruvian species could be marketed as ‘Pacific

Sardines' and conform to this standard. According to McDonald (2005) the EU complained that reference to the Codex standard did not take account of the negotiating history which had produced the standard, but this did not prevent a decision in favour of Peru.

The above example demonstrates the importance of Article 2.4 of the TBT agreement, which states that:

Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

In the case of sardine varieties, the Codex standard was considered to be the relevant international standard. Therefore Codex standards can assume an important role in the resolution of international trade disputes. Often, however, work on *setting* food standards is relatively uncontroversial, even if it is conducted on a topic that later proves to be controversial (the EU attempted to draw attention to this in the sardines dispute). The majority of food standard-setting activities may only be of an immediate interest to the relevant government delegations, industry representatives, consumer groups and small groups of experts including toxicologists, microbiologists, public health professionals, and international trade lawyers. Yet the process for negotiating food standards is an important component of the international trade in food under the WTO. As a result standard-setting is worthy of further scrutiny by social scientists.

According to Veggeland and Borgen (2005), the Codex has changed from a 'gentlemen's club', where international food standards were agreed with little disruption or controversy (even if parties disagreed), to an organisation in which negotiations have absorbed a strong political dimension, in line with WTO positions. The expectation of the SPS and TBT agreements is that standards agreed in standard-setting institutions – such as the Codex – will become the focus for regulatory harmonisation. Harmonising standards to those agreed in the Codex ought to result in a reduction in trade disputes. However, besides the scope for varying interpretations of the SPS and TBT agreement

and the standards they reference, the standards themselves have to be agreed upon through negotiations between states in other international organisations. Further discussion of the operation of the Codex and the procedure for agreeing international food standards will be developed in Chapter Three.

As has been discussed, international trade has become a powerful organising principle for production, yet multilateral trade negotiations have floundered. The inability of the WTO to foster agreement has led to the assertion by Grant (2003: 66) that:

...the WTO remains one of the weaker global governance agencies despite the way in which its opponents often characterise it. It remains more a 'Water Treading Organisation' than a 'World Terror Organisation'. Its secretariat can seek to facilitate agreement, but much still depends on bilateral mutual accommodations between the EU and the USA. Their stance in turn is driven to a large extent by their domestic politics. There is a stated intention to make the Doha Round 'a development round', but the underlying asymmetries of power that favour the developed world are unlikely to be easily changed.

The critique of Grant (2003) suggests that national regulatory systems may have an important role to play in the development of international standards. Standard-setting is not positioned as prominently as multilateral trade negotiations such as the Doha Development Round. Yet, as has been suggested, international standards are increasingly referred to in resolution of trade disputes and, importantly, may be associated with the reconfiguration of regulatory systems. It is the process of agreeing international food standards which is addressed directly in this thesis.

### 1.3 Thesis Structure

This introductory chapter has expounded the aims of the thesis and the main questions to be addressed. It has also examined how the development of international trade policy, within the process of economic globalisation, has exerted a greater influence over the regulation of food and agriculture. The remainder of the thesis is structured into seven further chapters.

Chapter Two deals with theoretical approaches to international agri-food regulation. In doing so it provides a critical analysis of previous work undertaken on the political

economy of the agri-food system, the role of experts in international regulation and the relationship between scientific advice and the agreement of regulation. The Chapter divides into four main sections. Section 2.2 details how the notion of an agri-food system has been interrogated within the field of political economy. It is suggested that a governance perspective on agri-food systems affords a more prominent role for the influence of expert networks and knowledge claims than more Marxist-oriented approaches such as food regimes. It is argued that the materiality of the agri-food system is a crucial factor in attempts to assert authority and control and as a consequence contestation over knowledge claims about the substance of the agri-food system need to be analysed. Taking cues from this argument, Section 2.3 explores the concept of epistemic communities, as developed by international relations scholars seeking to understand the contribution of experts to international policy-making which requires scientific and technical input. Although the concept makes an important contribution to recognising the role of authoritative knowledge claims within the establishment of international agreements, it fails to address the production of scientific authority. A critique of the concept is set out in Section 2.4, drawing upon work in the field of science and technology studies (STS).<sup>10</sup> The remainder of the Chapter discusses various alternative approaches to science and regulation within the STS tradition, including boundary work, the core-set of scientists and approaches to regulatory diffusion and cultures.

The context to the study and the methods used to conduct the research are discussed in Chapter Three. The chapter divides into three sections. In Section 3.1, the origins, organisation and operation of the Codex are detailed. This account of the Codex is provided in order to demonstrate how the functioning of the institution in which international food standards are agreed was an important consideration in the production of the case-study. The methodology for researching the process of international food standard-setting cannot be set out without considering the institutional conditions in which the case-study is located. Moreover – as is discussed in Chapter Seven – the operation of the Codex has a significant impact upon the standard-setting process. Section 3.2 is concerned with the research methodology. The value of a single, in-depth case-study approach is discussed. Attention is paid to the unfolding development of the

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<sup>10</sup> This field is regarded as including the sociology of scientific knowledge and the sociology/social shaping of technology.



case-study through scoping activities. A rationale is given for the use of interviews, observation and document analysis as research methods. The relationship between the case-study and the empirical analysis is considered in Section 3.3. Here it is suggested that the methodology employed to study the standard-setting process has a profound impact upon the empirical material produced and the type of analysis conducted. The section provides a brief introduction to the analysis presented in Chapters Four, Five and Six.

The empirical analysis begins with Chapter Four, which concentrates upon the treatment of dietary fibre as a regulatory dilemma within the Codex. Efforts to agree a definition of dietary fibre have important consequences for the ability of food companies to market new products which make health and nutrition claims. Moreover, dietary fibre has long been associated with a healthy diet and the consumption of fruit, vegetables and wholegrains. At stake is the definition of a nutritional category, the development of new food products and the reform of national and international regulation. Section 4.2 considers the history of the debate over dietary fibre within Codex committees, in particular the Codex Nutrition Committee. The section contextualises the account subsequently provided in Section 4.3, which deals with the process of standard-setting as it occurred in the 2007 Codex Nutrition Committee. Again, the focus here is upon the attempt to agree a definition for dietary fibre. Section 4.3 demonstrates how deliberations within Codex committees follow a particular methodology of standard-setting, a notion which is explored more fully in Chapter Seven. The importance of contributing to the standard-setting process through the formal submission of comments is detailed in Section 4.4.

Chapter Five is concerned with the history of scientific and technical discussions around dietary fibre. The introductory section – Section 5.1 – details some basic concepts in nutritional science. The chapter provides an analysis of the basis of the scientific contention which emerged within the standard-setting process and is divided into three major sections: discovering dietary fibre (Section 5.2), defining dietary fibre (Section 5.3) and disputing dietary fibre (Section 5.4). Discovering dietary fibre details the emergence of the dietary fibre concept amongst a core-set of scientists. Defining dietary fibre concentrates upon the subsequent attempts amongst the scientific community to agree a definition for dietary fibre and an associated method of analysis,

while also discussing the growing public awareness of dietary fibre as a nutritional concept. The final major section, disputing dietary fibre, gives an account of the spiralling contention between scientists over the definition of dietary fibre.

Chapter Six is the final empirical chapter and deals with the role of knowledge claims in the production of scientific advice to inform standard-setting in the Codex. As such the chapter builds upon Chapters Four and Five by concentrating upon the emergence of knowledge claims in four domains: the European Commission, the UK, the US and the FAO/WHO (Section 6.2). Section 6.3 develops the analysis of this material by considering the relationship between the production of knowledge claims and the application of scientific techniques. In particular, the act of measurement is conceptualised as a key influence upon any definition of physical properties. Finally, the implications of the concepts of boundary objects and immutable mobiles are re-introduced (from Chapter Two) in the analysis of the construction of a definition for dietary fibre.

In the discussion chapter – Chapter Seven – three main arguments are detailed. Firstly, as discussed in Section 7.2, Codex standard-setting is conceptualised as a methodology intended to facilitate agreement and the diffusion of regulatory systems. Secondly, as detailed in Section 7.3, the controversy over dietary fibre is considered to be a technical controversy. Technical controversies are those controversies located within regulatory processes, which build steadily over time and often over many years, and are characterised by a lack of wider public interest. It is suggested that technical controversies can be settled by the creation of a boundary object. Section 7.4 sets out the relevancy of the case-study for the development of governance approaches to the agri-food system. Here it is argued that further attention is required to the critical role played by networks of experts in the conduct of agri-food governance. However, adopting the epistemic communities approach in such studies is deemed to be problematic due to a failure to address the conditions giving rise to particular knowledge claims. Finally, Chapter Eight sets out the main conclusions of the thesis (Section 8.1) and details future research questions (Section 8.2).

## **Chapter Two – Theorising International Agri-Food Regulation**

### **2.1 Introduction**

In Chapter One the historical development of the international trade system was detailed in the context of economic globalisation. More specifically, the chapter dealt with those instruments of the trade system directly connecting food and agriculture with trade regulation. The purpose of this chapter is to develop an analytical framework through which to pursue questions arising from the context set out in Chapter One. Therefore, in this chapter the implications of the new international regulatory context for the agri-food system will be explored. The chapter divides into five further sections.

In Section 2.2 the origins of the concept of an agri-food system are explained. Work undertaken from a sociological and political economy perspective, which charts the changing social regulation and capital accumulation strategies within the food sector, is explored. The section reflects upon the emergence of governance approaches within studies of the agri-food system. It is suggested that this theoretical development reflects change within the agri-food system. Such changes are regarded as part of a broader shift in the way authority is exerted through expertise. Section 2.3 introduces the concept of epistemic communities as a method of understanding the role of experts in international regulation. Section 2.4 develops a critical analysis of the epistemic communities concept, drawing primarily upon work undertaken in the sociology of science and technology. Section 2.5 develops ideas introduced in section 2.4 by detailing some alternative perspectives on the relationship between science and policy. Section 2.6 concludes the Chapter.

### **2.2 The Concept of an Agri-Food System**

The starting point for discussing regulation and standards in global food governance is to detail how the political economy of food is arranged. Work undertaken from a political economy perspective has given rise to the concept of an agri-food system. The composition and structure of this system is illustrated in *Figure 2.1* on page 17. As

applied to the food system, the term political economy denotes a focus upon the organisation of capital accumulation and the institutions which regulate the market economy in food commodities and products. The regulation of the market in food goods has moved through various phases of development, whilst capital accumulation in the agri-food system has also been reorganised through political and technological developments. According to Whatmore (1995: 37) “...divergent experiences of the political economy of food are intimately connected; bound together in highly industrialised and increasingly globalised networks of institutions, technologies and products, constituting an agro-food system.” This definition of the agri-food system comprises several core features. Perhaps the most important is the global orientation of the agri-food system produced by ‘increasingly globalised networks’. This globalising, networked orientation increasingly defines the other core features of the agri-food system. For instance, ‘divergent experiences of the political economy of food’ captures the extent to which distinct national forms of agriculture and food supply have developed over time alongside other experiences. The connection of divergent experiences is perhaps a defining characteristic of what has been termed globalisation.<sup>11</sup>

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<sup>11</sup> According to Held (2004: 1), globalisation “...refers to a shift or transformation in the scale of human organisation that links distant communities and expands the reach of power relations across the world’s regions...the unevenness of globalisation ensures it is far from a universal process experienced uniformly across all countries.”

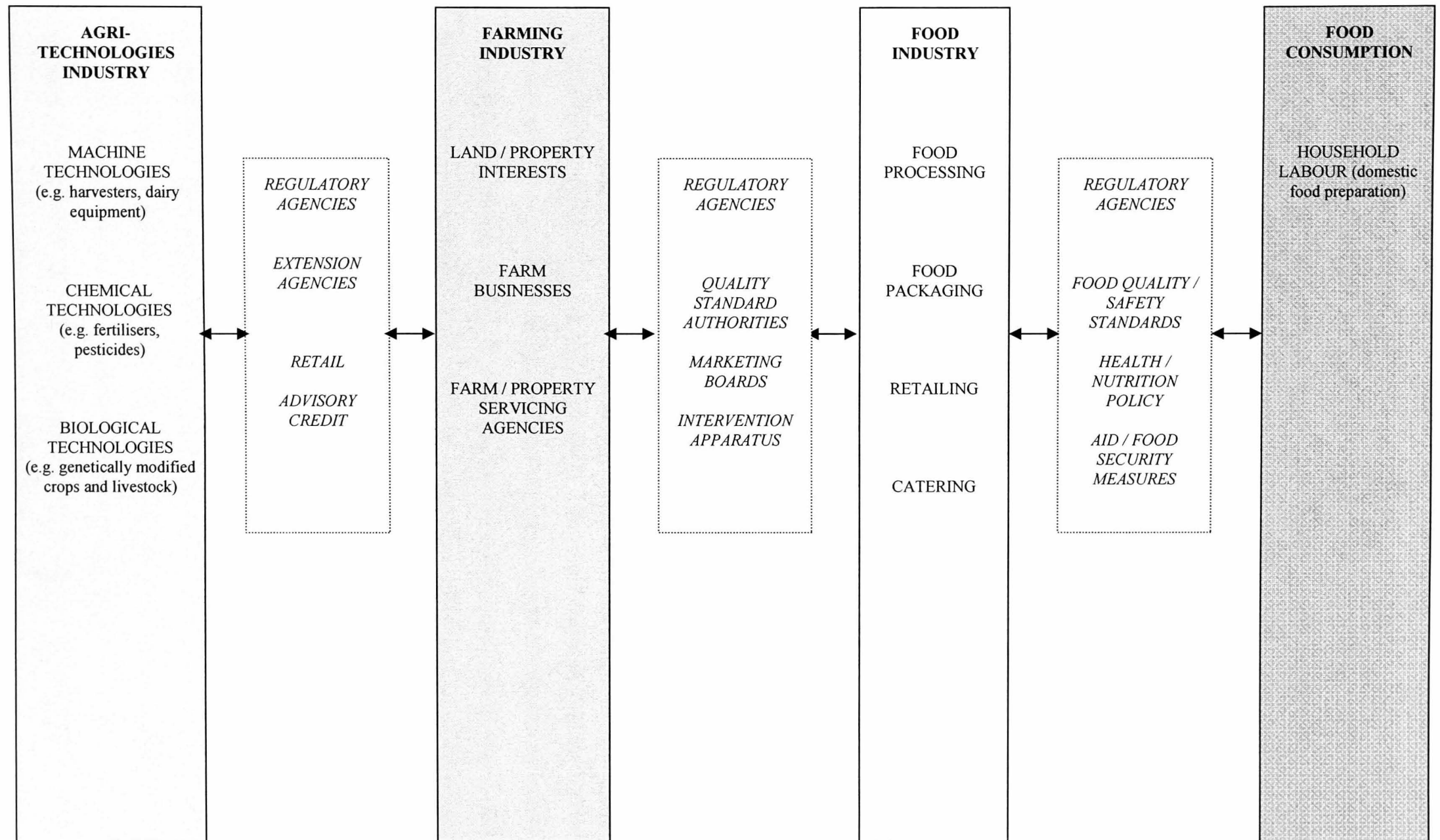


Figure 2.1: The contemporary agri-food system (adapted from Whatmore, 1995)

The conceptualisation of an agri-food system has emerged through a number of political economy and sociological approaches to change in agriculture and the food sector. Buttel (2001) identifies several theoretical clusters: neo-regulationist studies, food regimes, agri-food commodity chain analysis, actor-network approaches, farming styles / actor-oriented analysis and cultural-turn rural studies. His history of agrarian political economy identifies the growth of these diverse clusters as an “explosion/fragmentation of theoretical traditions.” (Buttel, 2001: 169). These distinct clusters are defined mainly by their relationship to political economy. Indeed, Morgan *et al* (2006) consider the main theoretical approaches to the agri-food system to be the political economy of commodity chains, actor-network theory and conventions theory. This broader classification ignores cultural-turn rural studies which are mostly pre-occupied with local and regional food systems.

The range of approaches to conceptualizing and elucidating the industrial agri-food system can be categorized by degrees of departure from a structuralist Marxist interpretation of political economy. The food regimes perspective, first developed by Friedmann and McMichael (1989), is perhaps closest to this structural interpretation. The food regimes perspective attempts to locate food and agricultural change in an account of the capitalist world economy and has been referred to by some as a regulationist approach to political economy. The food regimes perspective is deemed regulationist by placing emphasis upon international regulatory apparatus which support and guide the global market in food (Whatmore, 1995) and expressing “...the pivotal role of the food system in the periodic expansion and transformation of the global capitalist economy.” (Lowe *et al*, 1994: 7). Regulationist studies of agri-food systems are concerned with changing *state* practices and rules, the impacts of these changes upon agri-food systems and their relationship to structural shifts and ruptures (Buttel, 2001). Generally, the regulation approach deviates from formal structuralist Marxist political economy by proposing that capitalism is subject to periodic shifts in its development through crises and social conflict. These shifts can be understood as: changes to the *model of industrialisation* and therefore the organisation of labour, changes to the *regime of accumulation* comprising macroeconomic principles and changes to the *mode of regulation* which is constituted by institutional and cultural norms and rules (Lipietz, 1991). The regime of accumulation “...appears as the

macroeconomic result of the workings of the mode of regulation, based on a model of industrialisation.” (Lipietz, 1991: 462). Fordism is associated with a specific regime of accumulation, in that it refers to a settled configuration of political, economic and social relations – characterised by mass production, consumption and Keynesian economics – which dictate the accumulation of capital.

Others working from within agrarian political economy have also drawn upon the food regime perspective. Goodman and Redclift (1991) interpret two regimes of accumulation: the extensive and the intensive. The extensive regime, which occurred from the mid 1800s until the onset of the First World War, involved an expansion into overseas markets and agricultural production began to be reconfigured to meet the dietary and resource demands of industrialisation. Food processing emerged as a new logic in food production, spurred by advances in chemistry and engineering. They suggest that the intensive regime comprised a turn towards productivism, with a grain-livestock complex underpinning policies of cheap food production. Marsden *et al* (1993) also utilise the food regime perspective, identifying an 'Imperial' food order (1860s-1930s) and an 'Atlanticist' food order (1940s-1970s). The former is primarily a result of agricultural production being extended throughout the British empire of the period, whilst the latter emerges as a result of US hegemony over agricultural trade in combination with the desire of the UK and US to secure internal food security. The food regime perspective has provoked much discussion amongst agrarian political economists and sociologists. Goodman and Watts (1994) questioned the 'regimeness' of the food regime proposed by Friedmann and McMichael, in other words whether the global food governance structure was as coherent as the concept of a food regime suggested. Moreover, they draw attention to the diverse national modes of regulation and replications of agricultural specialisation throughout the world. They pose the question “...is the second food regime an adequate representation of multinational forms of accumulation and regulation?” (Goodman and Watts, 1994: 21). In a similar manner Marsden *et al* (1994: 107) have suggested that the food regime perspective “...ignores the fact that nationally constructed systems of regulation, food consumption, and legitimation are crucial in assessing the changes of direction and the relative sustainability of the international food system.”

A collection of essays published in the journal *Review of International Political Economy* tackled the disagreements over appropriate scales and styles of political economy approaches to food and agricultural change (Ward and Almas, 1997; McMichael, 1997; Goodman, 1997; Busch and Juska, 1997). The contribution of the regulation approach dominated these debates, with some authors suggesting that regulationist studies may have explanatory limits. For instance, Busch and Juska (1997), who advocate an actor-network approach, argue strongly that Marxist political economy (or 'critical political economy') fails to adequately deal with: the instability of agricultural change, human actors within and across institutions and the impact of technological change (and its production of 'action at a distance') and non-human actors such as plant varieties. In contrast, McMichael (1997) suggests that the agrarian question (the role of the peasantry and family farmers in capitalist development) is composed of national interpretations of a global process compounded by the construction of "supra-statal institutions". His theoretical position is one of Marxist political economy which places emphasis upon the "world-historical context". The current context of global institutions and weaker nation-states has, he argues, changed the terms upon which the agrarian question can be framed. The two papers demonstrate very different concerns. Busch and Juska (1997) attempt to transcend what they regard as fundamental deficiencies in Marxist political economy, without completely abandoning the framework of political economy, while McMichael (1997) continues to pursue a food regime perspective on the world-scale in order to illuminate new tensions, conflicts and configurations. Goodman (1997) calls into question the application of an *industrial* international political economy framework to the agri-food system, and specifically those of the regulation school. His novel take on contention over political economy and global agricultural change, derived from the work of Richard Gordon, is the differentiation between internationalisation (exchange logic), multi/transnationalisation (production logic) and globalisation (innovation logic) as concurrent processes. He suggests that within political economy approaches to agricultural change a lack of concern with foreign direct investment and corporate organisation has led to insufficient attention being paid to the production logic of multi/transnationalisation. Goodman (1997: 679) suggests that agri-food sectors are not characterised by an integrated hierarchy of production systems, adding that "...the fruit and fresh vegetables sector does not fit this industrial model of multi/transnationalisation and the role of biological and other environmental factors



[...] are likely to inhibit the prospects of it doing so in the future.” This question cuts to the core, often implicit, point of contention in debates over political economy approaches to the agri-food system: the role of science, technology and materiality in the food sector.

A recent edited collection on the sociology of the agri-food system suggested using the concept of ‘agricultural governance’ in order to denote a way of understanding and explaining how governing in the agri-food system is done through a mixture of private and public regulation (Higgins and Lawrence, 2005). The intended focus of this concept is upon the “...techniques and practices that make possible agricultural regulation in a globalising world.” (Higgins and Lawrence, 2005b: 1). In proposing the concept of agricultural governance, the authors draw upon definitions of governance from outside the sociology of the agri-food system. In doing so, the definition of governance and its applicability to the agri-food sector requires clarification. Firstly, whilst the authors have used the concept of ‘agricultural governance’ as the title of their collection, the featured studies employ the concept of the agri-food system and cover the full range of agricultural and food sector activities, from agri-technologies, to farming, to food processing through to consumers. By constantly moving between discussions of ‘agricultural governance’ and what can be termed ‘agri-food governance’, the authors risk weakening the cohesiveness of the agri-food system as a tool for analysing the interconnected elements of the agri-food sector. Therefore, the concept of agri-food governance will be retained in this chapter and in this current discussion of governance. Secondly, the definitions of governance discussed in developing the concept of agri-food governance are principally drawn from the work of Jessop (1995) and Stoker (1998). At the level of a general definition, Jessop (1995) suggests that a governance perspective involves a rejection of the conceptual separation of the market, the state and civil society. By way of example he notes the growing interest in international regimes as forms of political co-ordination reaching beyond the confines of autonomous state actions. The regimes approach to international relations is also a clear example of how a governance perspective implies a rejection of a coherent, higher-level organising process. As Jessop (1995: 319) states “in focusing on specific sets of inter-organisational relations, theories of governance imply that the macro-level is marked by an ungoverned (and probably inherently ungovernable), blindly evolving hybridity of governance systems.” In this way governance as an approach is varied and

turns upon the specifics of the governance systems of interest to the analyst. In consequence it is appropriate to construct agri-food governance as an analytical concept in the same way as economic governance, regional governance or health governance might be constructed.

Agri-food governance would therefore suggest a focus upon the inter-organisational relations of the agri-food sector. Stoker (1998) suggests that the governance perspective helps to clarify the changing nature of government without purporting to offer governance as a solution to government and identifies five elements of governance. Firstly, governance refers to a complex mix of institutions and actors from and beyond the state. It is suggested that, in the UK, a pre-occupation with the Westminster model of government (executive and legislature) has failed not only to recognise the diverse and complex sets of relationships which exist between different centres of government such as government agencies, local government, regional government and international institutions, but also has neglected the enhanced governing role of a multitude of private actors. Secondly, increasingly uncertain boundaries of responsibility for public welfare and prosperity exist within the state and between the state and other actors. Thirdly, institutions have become more interdependent and have to share and negotiate resources. Fourthly, governance implies the possibility of autonomous self-government. According to Rhodes (1996), the value of a governance perspective is in conceptualising self-organising inter-organisational networks, which he regards as of increasing importance to the act of governing. Such networks use resources such as money, information and expertise to ensure they achieve influence and desired outcomes. In this way, expertise is an important category of investigation from a governance perspective. Finally, Stoker (1998) regards the governance perspective as able to identify governing practices which do not rely on the direct use of authority. This occurs primarily through co-ordination, steering, integration of actors and, importantly for this study, the use of regulation.

The use of a governance perspective on the agri-food system is discussed by Peine and McMichael (2005). They regard the turn to governance as being associated with globalisation, stating that: "The historical context for this extended meaning of governance is the deterritorialisation of space, through the deepening of market relations." (Peine and McMichael, 2005: 19). They suggest that globalisation is a

political project intended to reduce state interference in the market to be achieved by increasing commodification, locking capital into transnational firms and privatising public institutions.<sup>12</sup> In this sense it is suggested that governance is merely the management of market relations. They argue that states are complicit in protecting the interests of large, transnational firms and that governance is merely a rhetoric describing the tools which are being used to achieve this. These tools include multilateral and bilateral trade agreements, such as the intergovernmental Agreement on Agriculture administered by the WTO and the North American Free Trade Agreement (NAFTA). Governance of the agri-food system in the context of globalisation is thus described as a discursive device “that seeks to legitimise a state-authored global project of corporate agriculture” (Peine and McMichael, 2005: 32). The critique of governance by Peine and McMichael assumes that there exists a triumphant neo-liberal project operating at a global-scale – actualised through international agreements – which is restructuring the entire agri-food system. Viewed from this mode of analysis, what can a governance perspective offer? The self-organising, inter-organisational networks identified by Rhodes (1996) become little more than minor characters to the world-scale power play of states and transnational firms. How then do these states and firms generate the conditions for the ‘market rule’ of global agribusiness and how is such rule constituted? The importance of self-organising networks to governing is asserted by Cheshire and Lawrence (2005) who identify with a governance perspective which understands the state as being comprised of many associated networks operating within particular fields of interest. In this way the state is a much more tentative category which has to be constantly reassembled and remade in order for actions to be taken. According to Rose (1993), a defining characteristic of liberal democratic states is the proliferation of self-organising networks which form around shared notions of expertise. He regards these networks, which may seem insignificant or unidentifiable from a world systems perspective, as important in producing the systems of rule that constitute authority.

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<sup>12</sup> According to some the changing role of the public sector does not merely involve the direct transfer of state-owned assets and competencies to the private sector. Rhodes (1996) draws attention to the growth of public regulatory agencies and the simultaneous rise of managerialism within the public sector. Managerialism involves the introduction of methods employed in the private sector – such as professional standards and performance measures – into the public sector.

From this perspective, there is no single state which exerts authority. Instead:

a diversity of types of authority have been invented, justified in different ways, and with different relations to their subjects. And, of course, so many of those who are subjects of authority in one field play a part in its exercise in another.

(Rose, 1993: 287)

The accounts offered by Peine and McMichael (2005) and Cheshire and Lawrence (2005) differ in their conceptualisation of the location of authority. In the former approach, authority resides with powerful and coherent states (e.g. US) in collaboration with powerful and coherent transnational firms (e.g. Cargill). In the latter approach, authority is more diffuse and tentative and the concern of the piece is not to build an account which generates powerful actors but instead to examine carefully the constituent elements of governing processes.

### 2.3 Expertise and International Regulation: The Role of Epistemic Communities

The importance of self-organising networks of expertise to international policy co-ordination – such as the formulation of international conventions, agreements and standards – has been identified by some international relations scholars. Frequently this co-ordination occurs around scientific and technical issues e.g. food safety, environmental pollutants or communicable diseases. These issues require the input of specialists in order to provide evidence on the scientific problem. The concept of epistemic communities has been employed to develop analyses of how international agreements are formulated in particular policy domains through the contribution of these expert groups. Haas (1992a) defined epistemic communities as “...a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within the domain or issue-area.” (Haas, 1992a: 3). He also set out the four characteristics which epistemic communities exhibit. They are: a shared set of normative and principled beliefs, shared causal beliefs, a shared notion of validity and a common policy enterprise. The first three

characteristics are principally internal to the community. Normative and principled beliefs give the epistemic community a social rationale – they become certain that the correct application of their understanding will be 'for the best'. Causal beliefs are central to the epistemic community concept and are produced by claims to truth being challenged within the community until an agreed understanding about 'how this problem is manifest' is reached. Finally, the assessment of causal beliefs is achieved by shared notions of validity. Notion of validity are the criteria for assessing truth claims.

On the basis of the four characteristics detailed above, an epistemic community projects into a common policy enterprise. This is the focus of practice for the epistemic community – it is where their communal expertise is directed. Epistemic communities are important when international problems are associated with scientific and technical uncertainty, in policy arenas in which problem-solving ideas can have a significant impact upon decisions. In short, Haas (2004) suggests that knowledge-based experts and professionals are involved in communities that lay claim to authority in policy domains relevant to their expertise and describes these communities as transmission-belts of like-minded scientists. If primacy is given to shared causal beliefs as the underpinning principles of epistemic communities, then epistemic communities only exist when scientific or technical knowledge is required i.e. not in matters of ethics or morality. Without the need for science to provide analysis supporting particular claims there is no reason for an epistemic community to exist. Epistemic communities only come together around scientific and technical uncertainty and are therefore particularly important when the governance of a policy domain involves science and technology. The regulation of the agri-food system is one such domain.

The concept of epistemic communities has been explicitly utilised or discussed in a number of studies (e.g. Adler, 1992; Adler and Haas, 1992; Drake and Nicolaidis, 1992; Haas, 1992a, 1992b, 2004; Haas *et al*, 1993; Hasenclever *et al*, 2000; Hopkins, 1992; King, 2005; March and Olsen, 1998; Petersen, 1992; Sebenius, 1992; Verdun, 1999; Zito, 2001). In order to demonstrate the use of the concept, it is helpful to examine three of these studies (Haas 1992b; Hopkins, 1992; Petersen, 1992) in more detail. Petersen (1992) undertakes a study of expert groups and international regulation in the whaling sector, Hopkins (1992) employs epistemic communities in a discussion of the international food aid regime, whilst Haas (1992b) uses the concept in an analysis of the

1987 Montreal Protocol on Substances That Deplete the Ozone Layer, an international agreement which called for significant limits on the production and use of chlorofluorocarbons (CFCs). These three studies formed part of a special edition of *International Organisation* published in 1992 on the theme of epistemic communities. The dimensions of the epistemic community concept and their use within these studies can be seen in figure 2.2:

	Haas (1992b)	Petersen (1992)	Hopkins (1992)
<b>Epistemic Community</b>	Ecological	Cetological	Food Aid
<b>Normative Belief</b>	Atmospheric Protection	Conservation of Whale Populations	Poverty Alleviation
<b>Causal Belief</b>	Rowland-Molina Hypothesis	Biological Studies	Development Economics
<b>Validity Belief</b>	Scientific Method / Peer Review	Scientific Method / Peer Review	Seminars, Conferences / Peer Review
<b>Policy Project</b>	The Montreal Protocol	International Convention for the Regulation of Whaling	World Food Programme

*Figure 2.2 Comparison of three epistemic communities and their constituent elements*

Each study identifies an epistemic community, though the composition and dimensions of these communities is open to change over time. For instance Petersen (1992) identifies a cetological epistemic community in the regulation of whaling but emphasises that this grouping did not remain static. Cetologists – scientists who study marine mammals – were involved in the early years of international whaling regulation and shared many causal beliefs held by senior managers from whaling firms. However, they differed from the commercial interests by emphasising the importance of the long-term survival of whaling populations large enough to maintain a whaling industry. During the early years of the International Whaling Commission (IWC) in the 1950s, the cetologists lacked agreed models and data sets of sufficient size to make credible claims to support their longer-term perspective. In the 1960s a change in the scientific committee structure of the IWC and the recruitment of cetologists favouring population modelling led to a stronger push for changes to quotas. Other cetologists sought even quicker change on quota levels and by the 1970s cetologists favouring preservationist policies were being subsumed as an epistemic community by environmentalist movements. With a rapid drop in whale stocks during the 1970s new procedures were introduced for the IWC which enhanced the role of data and population modelling to the

regulatory process. This important change increased the time spent debating scientific evidence and increased the use of scientific debate within decision-making. The cetological epistemic community anticipated that these changes would afford them greater influence in the regulation of whaling, but growing public interest in the issue galvanised environmental groups pushing for zero-level quotas. At the same time, rapid developments in multi-species modelling weakened the causal beliefs which had unified the cetologist epistemic community. Some cetologists abandoned the original approach of setting quotas to ensure viability of long-term commercial whaling (the conservationist position) and instead joined claims for a moratorium. An inability to deal with scientific uncertainty in the new IWC procedures and the use of uncertainty by environmental groups as a support for banning whaling lead to the cetologist epistemic community fracturing and becoming increasingly involved in matters beyond the narrow confines of marine biology, such as critiquing the notion of resource management. Petersen (1992: 170) suggests that:

The divisions became so deep that cetologists did not operate as a unified group in the 1974-82 period. Internal disagreements about which model to use and how to interpret the data made it difficult to give the unified advice necessary to counter the influence of either industry-oriented members of the IWC Scientific Committee or the environmentalists...the arguments among cetologists meant that they could not frame the policy choice by expert application of agreed canons of validity to agreed model and data on the basis of shared principles and policy preferences.

A zero quota was adopted after a significant struggle in 1982 and took effect in 1986. It was retained after a review in 1990, although important exceptions existed such as scientific permits for whaling. In concluding his analysis, Petersen (1992) suggests that whilst the regulation of whaling is an international policy domain in which epistemic communities ought to feature heavily – due to the ability to measure, observe and predict populations – cetologists never asserted a strong influence. Instead he recognises that through forty years of regulatory reform the cetologist epistemic community exerted different forms of influence; counterbalancing industry preferences in the 1950s, encouraging a conservation perspective in the 1960s and limiting the preservationist drive in the 1970s and 1980s. He suggests that these fluctuations were due to the weak institutions involved (the IWC), the changing political process and in dynamics internal to the epistemic community itself.

In a second study featured in the same special issue, Hopkins (1992) details the formation of a developmentalist epistemic community concerned with the provision of food aid. Members of this community were principally development economists and administrators seeking to steer food aid to support long-term development rather than short-term fixes for food shortages and food surpluses. In identifying how this epistemic community was configured, Hopkins (1992) draws attention to prominent individuals such as Sir Hans Singer. A 1983 seminar on food aid which took place in The Hague is deemed to be of particular importance and a list of participants is included as evidence of the community's membership. The developmentalist epistemic community is distinguished from a separate critical epistemic community which emerged during the late 1970s and advocated the abolition of food aid. The developmentalist epistemic community sought to adjust and improve the distribution of food aid. This work was undertaken in four areas of concern: disincentives, resource transfers, allocation and conditionality. In the first area, the impact of food aid was said to create a disincentive for domestic food production. The epistemic community sought to demonstrate that this could be overcome if the food aid provided stimulated food demand amongst the recipient countries' population. In the second area, an argument was made that providing aid in the form of food could be an efficient transfer of resources if a range of pro-active mechanisms were used, including monetisation. This involves food being shipped to recipient countries for sale in local markets. In the third area, the publication of studies by the developmentalist epistemic community, such as the USDA's World Food Needs and Availabilities, gave justifications for food aid being targeted towards those countries most in need. In the fourth area – conditionality – the epistemic community was judged to be in a stage of confusion. Conditionality denotes the linking of food aid to other macroeconomic requirements such as structural adjustment, which was met by some opposition. According to Hopkins (1992: 262) "Given this opposition, the epistemic community has not yet been totally successful in establishing a clear priority for food aid to address long-term hunger problems by linkage to food policy reform, although some movement toward this goal has occurred." In summary, Hopkins (1992) suggests that the epistemic community has been responsible for 'reshaping' the food aid regime. The studies undertaken by this group have successfully supported an approach to food aid policies which involves careful design. In this regard, food aid policies ought to consider the four areas of concern outlined previously. Hopkins (1992) notes that the developmentalist epistemic



community initiated definite incremental changes to the food aid regime even when advocating approaches which were politically unpopular.

The studies by Petersen (1992) and Hopkins (1992) both identified epistemic communities, but the fortunes of these groups followed distinct pathways. The cetologist epistemic community suffered fragmentation due to the emergence of new methods and models which impacted upon the shared notions of validity, whilst the developmentalist epistemic community remained relatively coherent as group through the strength of the shared policy project. From these two case-studies it can be asserted that the four elements of an epistemic community identified by Haas (1992a) – shared causal beliefs, normative beliefs, notions of validity and a policy project – matter in different ways and to varying degrees depending upon the case in question. In the case of cetologist epistemic community, the development of more complex population models produced pressures in the shared notions of validity which had implications for the shared normative beliefs (tensions between conservation and preservation of whale populations). In the case of the developmentalist epistemic community the group maintained its cohesion through consensual knowledge and a focus upon the distribution of food aid. The normative beliefs and policy project were important elements here and shared notions of validity were renewed over time through seminars, conferences and administrative work. In a third study of an epistemic community, Haas (1992b) regards an ecological epistemic community as being very influential in co-ordinating national policies towards the Montreal Protocol, which called for the elimination of chlorofluorocarbons (CFCs). The normative and principled beliefs of the epistemic community involved a desire to preserve the quality of the environment. In terms of causal beliefs, the epistemic community accepted the Rowland-Molina hypothesis that chlorine reacts with ozone molecules and depletes stratospheric ozone. Shared notions of validity came from an acceptance of the use of appropriate scientific methods. They were motivated by a shared belief that ozone depletion should be halted and so their common policy project involved strongly regulating CFC use. In a situation similar to that described by Petersen (1992), Haas (1992b) suggests that the ecological epistemic community showed divisions along conservationist and preservationist lines. The conservationists focused upon the control of CFCs, whilst the preservationists sought broader reductions on all environmental contaminants. Interestingly Haas (1992b) suggests that atmosphere scientists were not the only

members of the ecological epistemic community. He includes officials of the UN Environment Programme and the US Environmental Protection Agency as members even though they did not have training in atmospheric science. The inclusion of non-specialists within an epistemic community draws attention to the importance of belief in defining the group. This includes causal and normative beliefs. Members do not necessarily have to be competent in conducting the science involved in an issue of concern, but instead must share a belief in the argumentation of causes and validity. Sebenius (1992) regards epistemic communities as being more concerned with the realisation of a policy project than with the material conduct of science. Similarly, Gough and Shackley (2001: 332) suggest that “Scientific knowledge is the 'glue' that helps to keep policy actors committed and can be used as a trump card against opponents to the epistemic coalition.” This blurring of scientific knowledge and political process does not mean that scientific knowledge can be used totally instrumentally, nor that scientific knowledge is merely a construct. Scientific knowledge does reveal things about the world which can not be created or dismantled absolutely by political processes, but the political process can alter the terms upon which the knowledge is created and used. In this way it becomes increasingly problematic to regard science and policy-making as separate domains.

## 2.4 Critiques of the Epistemic Communities Concept

As suggested in the previous section, epistemic communities are said to exist when a network of professionals, with recognised expertise in a specific field or domain, can make an authoritative claim to policy-relevant knowledge (Haas, 1992). The premise of the concept of epistemic communities is that expert professionals can be recognised in a particular field by all others involved in that particular field and, with this support, can influence international policy decisions on the basis of agreed science. Despite focusing attention upon the importance of knowledge to international policy-making, it has been suggested that the concept of epistemic communities fails to address how expertise and authority come to be produced through on-going epistemic and political contestation. According to Jasanoff (1996b: 174) “The literature on the policy-making role of transnational scientific communities, for instance, seems almost complacent about entrusting power to such knowledge elites.” Lahsen (2004) suggests that within science

and technology studies (STS), critiques have been developed which assert that the concept of epistemic communities fails to recognise the role of shared disciplinary orientations, economic interests, discursive framings and ideologies upon the production of shared understanding. In this section, the criticisms applied by STS scholars to the epistemic communities concept are considered. The main tension between the two approaches arises from the manner in which science is conceptualised as an activity.

According to Haas (1992), the concept of epistemic communities possesses commonalities with Kuhn's notion of a scientific paradigm (Kuhn, 1962/1996) and Fleck's notion of a thought collective (1935/1979), in that it emphasises the role of shared knowledge in the formation of groups. He states that: "Our notion of epistemic community somewhat resembles Fleck's notion of a thought collective – a sociological group with a common style of thinking. It also somewhat resembles Kuhn's broader sociological definition of a paradigm." (Haas, 1992: 3). However, both Kuhn and Fleck are heavily referenced within STS literatures and studies, including those explicitly critical of the epistemic communities concept. Kuhn is cited as the most renowned critic of formalistic accounts of science, which fail to recognise or acknowledge the contingency of scientific work (Sismondo, 2004). Writing about the influence of Fleck, Hacking (1999: 60) states:

He wrote of the emergence and development of scientific facts. He did not mean just that they emerge in human consciousness and develop in the history of science. He meant that the world does not come with a unique prepackaged structure.

In this respect both Kuhn and Fleck can be regarded as developing powerful challenges to the uncritical acceptance of scientific knowledge and its production. According to Pickering (1992), the works of Kuhn and Fleck (along with Polanyi (1958) and Bachelard (1934/1984)), represent the few early instances of prolonged engagement with the sociological and philosophical implications of science as a cultural activity.

For Kuhn (1962/1996), the establishment of a scientific paradigm emerges from two conditions: scientific achievement sufficient and coherent enough to attract an enduring group of adherents (to the detriment of other groups) and also sufficiently open-ended to leave the group problems for future work. The stabilisation of a paradigm leads to the

undertaking of what Kuhn terms 'normal science'. Under normal science, scientific activity occurs in an incremental and cumulative manner until the next paradigm shift occurs. For Kuhn, normal science involves 'mopping-up' activities resulting from the open paradigm. Such activity, he suggests, pre-occupies most scientists for their entire careers. The conduct of normal science helps to support the view that science follows a steady, linear progression. When problems begin to occur within a scientific paradigm (a paradigm is only ever a temporary state of affairs) and those undertaking work outside of an established paradigm offer alternatives, Kuhn (1962/1996: 148) proposes that:

The proponents of competing paradigms are always slightly at cross-purposes. Neither side will grant all the non-empirical assumptions that the other needs in order to make its case...The competition between paradigms is not the sort of battle that can be resolved by proofs.

Scientific paradigms thus enter a period of crisis and revolution before a new paradigm is settled and the process begins again.

Although Haas (1992) aligns the concept of epistemic communities with notions of scientific paradigms and thought collectives, for Kuhn (writing in the foreword to the English translation of Fleck (1935/1979)), the relationship between his notion and Fleck's is not unproblematic. Fleck (1935/1979: 39) states that the notion of a thought collective comprises "a community of persons mutually exchanging ideas or maintaining intellectual interaction." As a result he suggests that a thought collective "provides the special carrier for the historical development of any field of thought, as well as for the given stock of knowledge and level of culture." A thought collective is thus the carrier for what is termed 'thought style'. However, Kuhn suggests that notion of a thought collective is misleading, in that it places emphasis upon individuals possessing logical knowledge, which then allows access to the collective and in turn strengthens the authority of that group. Such apparent emphasis upon individual psychology is not supported by Kuhn.

The problematic relationship between notions of scientific paradigms and thought collectives is taken up by Latour (2008). He suggests that the notion of scientific paradigms is misconceived, in that it separates the knowing subject from the thing in

itself. By separating subject from object in knowledge production, Latour (2008) asserts that the notion of scientific paradigms fails where the notion of thought collectives succeeds; in pursuing the emergence of a fact itself. In other words, Fleck is more concerned with how representations are produced. Latour (2008: 92) suggests that: “Fleck does not say that we have a mind zooming toward a fixed – but inaccessible – target. It is the fact that occurs, that emerges, and that so to speak, offers you a (partially) new mind endowed with a (partially) new objectivity.” The suggestion of Latour (2008) is that Kuhn’s scientific paradigms are too static a conceptualisation of scientific knowledge production, given the emphasis upon periodic revolutions transforming normal science. Instead, Fleck’s analysis pays close attention to the construction of scientific facts themselves and so iteratively engages with subject and object. Indeed, Latour (1987) refers to the collective work which comprises fact-building as an activity.

Where does this leave the STS critique of epistemic communities? Haas (1992) invokes the notions of scientific paradigms and thought collectives in order to develop the concept. However, the approach of Fleck (1935/1979) is to pay close attention to the manner in which scientific facts are constructed. In contrast, epistemic communities are said to exert authoritative claims to knowledge, which they then locate within a policy project. In this regard, the contestation involved in the construction of scientific authority would seem to pose severe problems for the concept of epistemic communities. Jasanoff (2004) suggests that Kuhn is often credited with having instigated STS, while the influence of Fleck is well acknowledged amongst STS scholars. However, the specific events and interactions which comprise the conduct of science were not the focus of Kuhn. As Haas (1992) recognises in the passage quoted previously, the notion of scientific paradigms has a broader sociological lens than that of thought collectives as proposed by Fleck. The difference is a significant one when considering how scientific knowledge production relates to policy-making.

It is the assertion of Jasanoff (1996b) that the concept of epistemic communities places too much emphasis on consensual scientific knowledge and as a result fails to engage with the means by which groups of experts interact in order to exert (or fail to exert) authoritative claims to knowledge. In a later piece she suggests that attention to such issues has become a primary focus of STS studies, often rooted in the approach first

detailed by Fleck (1935/1979) (Jasanoff, 2004). Using the term co-production – which has origins in the work of Latour (1992) - she suggests that much STS work is now focused upon the question of how science and society are mutually constitutive. Co-production is said to describe how natural and social orders produce one another. She suggests that:

Knowledge and its material embodiments are at once products of social work and constitutive of forms of social life...scientific knowledge in particular is not a transcendent mirror of reality. It both embeds and is embedded in social practices, identities, norms, conventions, discourses, instruments and institutions.

(Jasanoff, 2004: 2-3)

The co-production approach to science and technology acknowledges that scientific controversies are rarely confined to the laboratory and seeks to ensure that wider political and institutional processes are centrally placed within analysis (Jasanoff, 1996a). In one example of how this approach can be applied, Jasanoff (1996a) discusses how scientists at International Life Sciences Institute (ILSI) drew upon Mertonian<sup>13</sup> norms of disinterested and objective science to discredit a legislative process as not being based upon science. In doing so, the ILSI scientists cited as a source of support an article published by Jasanoff which discussed this particular piece of legislation. Jasanoff (1996a) reflects upon methods by which ILSI actors drew Jasanoff into their problematisation of a political process. In suggesting the notion of coproduction, Jasanoff attempts to move away from the focus upon controversies comprising binary designations of winners and losers, in order to examine more closely how participation in particular controversies is made possible by particular institutional configurations. The questions of science and policy interaction will be dealt with more thoroughly in the following section.

Critiques of the concept of epistemic communities have focused upon the overly sympathetic analysis it affords to scientific consensus. In the previous section, Petersen (1992) – who provides an account of an epistemic community of cetologists operating in the area of the regulation of commercial whaling - suggests that epistemic

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<sup>13</sup> Merton (1973) sets out a number of norms which science adheres to: communalism, universalism, disinterestedness and organised scepticism. The Mertonian norms are idealistic characteristics of scientific activity.

communities can be open to fracture if disagreement occurs over scientific methods. The emphasis of Petersen (1992) is upon how scientists mobilise, or rather how they fail to mobilise, against political decision making which does not take account of scientific evidence. The concept of epistemic communities emphasises the ‘truthfulness’ of scientific knowledge claims as compared to the negotiations of international policy making which, by implication, undervalue scientific input. As a result of this emphasis upon consensus amongst scientists to get the ‘right’ advice through to the politicians, the concept of epistemic communities fails to address the means by which scientific controversy is produced and the impact this has upon the policy-making process. A pre-occupation with policy co-ordination based on scientific advice means that the concept of epistemic communities draws upon a sociological analysis which fails to interrogate the production of scientific advice. Yearley (2005) suggests that authors who draw upon the concept of epistemic communities can be critiqued on the basis of making idealistic and naïve assumptions about science, in particular science used to give scientific advice.

The critique of such an approach is supported – indirectly – by Majone (1989). Referring to the concept of ‘trans-science’ (Weinberg, 1972), he suggests that regulatory processes which take place at the intersection of science, technology and politics inevitably produce different claims over, and criticisms of, scientific evidence. The proposal of Weinberg (1972: 209) is that trans-scientific questions are:

epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science. In so far as public policy involves trans-scientific rather than scientific issues, the role of the scientist in contributing to the promulgation of such policy must be different from his role when the issues can be unambiguously answered by science.

The question of trans-science contributes to another problem; not only are knowledge claims produced in a non-linear way, in addition science cannot necessarily answer the questions it proposes in policy-making domains. Viewed from such a perspective, international policy-making comprises a complex set of interactions derived from varying scientific and political contexts. While these conflicts may be present in a national regulatory arena, the scope for tension is greater within an intergovernmental setting due to historical, cultural and political tensions and solidarities. In order to reach

final decisions on standards these conflicts and tensions have to be overcome through negotiations which rely heavily upon input – and even guidance – from experts.

It has been suggested that the concept of epistemic communities does not sufficiently recognise the role of conferment in establishing expertise, nor the professional context in which experts operate. This is particularly true if experts become significant political-scientific actors, as opposed to merely technical actors. In one such critique Antoniades (2003) suggests that epistemic communities can only be considered within their on-going professional and political contexts (rather than epistemic communities just forming and appearing around an international policy problem as suggested by Haas (1992a)). Recognition of authority over knowledge is thus a defining characteristic and the identification of a defining methodology becomes less important. As the studies by Petersen (1992), Hopkins (1992) and Haas (1992b) indicated, epistemic communities did not become fixed upon a single scientific methodology or hypothesis, but instead adapted and developed shared beliefs of causality and validity over time as science and the political context changed. Instead, Antoniades (2003) retains the constitutive elements of epistemic communities as devised by Haas (1992a), but prioritises the normative beliefs and policy project of the community above the shared causal beliefs and notions of validity. In considering and developing upon the original concept of epistemic communities, Antoniades (2003) considers two interconnected levels of operation: the cognitive (the construction of realities) and the practical (the interactions of the political process). In terms of the cognitive level, the suggestion is not that technical realities do not exist, rather that they are heavily mediated by those with the cognitive authority to make knowledge claims about their existence. The production of cognitive authority will be further explored in the following section.

## 2.5 Science and Regulation: Alternative Approaches

### 2.5.1 Boundary Work

As suggested in the previous section, powerful critiques of the epistemic communities concept have emerged from the field of STS, despite attempts to align the concept with



the work of Kuhn and Fleck. The concept is regarded as being unable to account for the production of scientific knowledge and the manner in which such knowledge is produced and articulated within policy-making. As Antoniadou (2003) notes, the struggle over cognitive authority in policy-making is not easily divisible between science and policy. According to Jasanoff (1987: 199), and following Gieryn *et al* (1985), cognitive authority involves an active process of boundary maintenance as “To shore up their claims to cognitive authority, scientists have to impose their own boundaries between science and policy, thereby coming into potential conflict with policy-makers pursuing opposing interests.”

The construction and maintenance of boundaries between science and non-science has been explored by Gieryn (1983) by employing the notion of boundary work. He suggests that boundary work is undertaken to produce such divisions. Boundary work, in this sense, involves the activities undertaken to demarcate who is inside a knowledgeable group and who is outside, thus establishing authority over knowledge claims. The approach of Gieryn (1983) emerges from dissatisfaction with previous sociological attempts to identify the inherent properties of scientific activity, as distinct from other forms of intellectual work. Instead, his interest is in the processes by which scientific activity acquires the status of producing authoritative claims to knowledge. As science becomes increasingly implicated in policy-making, Gieryn (1983) suggests that the construction of boundaries between science and non-science helps to insulate scientists from the consequences of the use of science in policy-making. However, the ability of scientists to deploy boundary work to protect their professional and expert status is undermined under conditions of scientific uncertainty or controversy. When such circumstances emerge, the authority of science becomes difficult to maintain.

The questions raised by the notion of boundary work will be revisited in Section 2.5.5. There it will be suggested that boundaries can be constructed and maintained, but can also be transgressed by boundary objects. In the following three sections (Sections 2.5.2, 2.5.3 and 2.5.4), several conceptual approaches to the role of scientists, regulators and institutions in the production of regulation will be detailed.

### 2.5.2 The Core-Set of Scientists

As Kuhn (1962/1996) suggests, scientific paradigms are frequently revolutionised and as a result normal science is periodically unsettled. In such circumstances, controversy often exists amongst scientists. The conduct of scientific controversies has been considered by Collins (1981) through the notion of the core-set of scientists. For Collins, scientific controversy over experimental design and conduct involves a small set of scientists actively involved in making scientific contributions to the controversy in question, which he terms the core-set. The emphasis upon 'set', rather than 'group', is deemed important as members of a core-set may be professional 'enemies' who seldom interact. As a result, competition is the definitive driver of the core-set. For Collins (1981), the core-set is thus of a different kind from those which emerge in the production of new paradigms or from those which Crane (1972) has termed 'invisible colleges'.<sup>14</sup>

The notion of a core-set highlights the role of competition and controversy within scientific knowledge production. According to Pinch and Bijker (1984), a 'knock-down' argument is rarely provided that will create harmony amongst the core-set and instead controversies are settled in terms of closure and stabilisation. Closure is considered to occur in two forms: rhetorical closure and closure by redefinition of the problem. Rhetorical closure occurs when a definitive proof or 'knockdown' argument emerges within a particular scientific problem. However, rhetorical closure does not necessarily mean that scientific consensus has been achieved. Importantly, Pinch and Bijker (1984) suggest that it is rare for such closures to resolve contention between scientists who are closely involved in the issue. Those scientists most involved in a particular scientific controversy may continue to disagree even after most other interested parties regard the issue as closed. The core-set are deemed to seldom reach a point of agreement in instances of scientific controversy and so the debate is ended by the force of rhetoric; persuasive arguments are employed to bring about a general sense of finality. Rhetorical closure may involve other groups of scientists who are outside of the core-set. According to Collins and Evans (2002: 241):

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<sup>14</sup> An invisible college is a communication network of scientists who share ideas in a collaborative enterprise within particular fields of scientific activity (Crane, 1972).

A *core-set* has been defined as being made up of those scientists deeply involved in experimentation or theorization which is directly relevant to a scientific controversy or debate. A core-set is often quite small – perhaps a dozen scientists, or half-a-dozen groups. A *core-group* is the much more solidaristic group of scientists which emerges after a controversy has been settled for all practical purposes.

The earlier distinction by Collins (1981) between a ‘set’ (which exhibits relatively low-levels of interaction) and a ‘group’, is thus developed to allow for core-sets and core-groups. The core-group involves core-set scientists and other scientists recognised in a settled field, conducting normal science (Kuhn, 1962/1996). Collins and Evans term these scientists the ‘core-scientists’. Significantly, Collins and Evans (2002) apply this approach to “esoteric sciences”, citing the detection of gravitational waves or the detection of solar neutrinos as examples of such high-level activity in the physical sciences. They go on to detail how the attempt to open up technical decision-making to broader forms of expertise (which they term the problem of legitimacy) has been replaced by the apparent erasure of differentiated forms of expertise. They consider this current situation to be located in a problem of extension. As a result, valued forms of expertise, which may have a distinctive contribution to make to decision-making, are offered the same parity as any other judgement. For Collins and Evans (2002), the implication of this extension of expertise is highly problematic. In particular, the designation and protection of esoteric science is deemed critical and they suggest that: “Should any politicians ever want to dismantle the right of the scientific community to settle esoteric issues within science, we would want to fight them.” (Collins and Evans, 2002: 243).

Although the concept of epistemic communities has been criticised for failing to account for the contestability of knowledge claims, the notion of core-set scientists (Collins, 1981; Collins, 1985; Collins and Evans, 2002) is also problematic. Following the terms used by Collins and Evans (2002), core-set scientists are not necessarily only concerned with working in the laboratory; they may be very interested in the ‘external’ politics into which their work is placed. In a critique of the notion of the core-set, Jasanoff (2003: 395) suggests that:

If we regard the very formation of expert ‘core-sets’ as a political phenomenon, then attention inevitably has to focus on the processes by which such sets are created, maintained, patrolled, and protected. In many areas of public policy, we

may not be interested in re-examining the foundations of settled expertise in this way, but when controversy erupts, it becomes important to ask what sustains the authority of a particular group of experts and their expertise.

The authority of groups of experts and their expertise is not a question readily engaged by either the concept of epistemic communities or the concept of core-set scientists. The former does not consider in any detail the constitution of scientific activity, the latter accords a protected, internalised space to a small group of scientists working on esoteric science. Neither is satisfactory, as both concepts fail to account for the role that institutions and the political process have in the shaping of expertise and the conduct of science.

When scientific controversy is situated within political controversy, scientific claims about knowledge can lose their appeal to objectivity. The idea that science provides unambiguous claims about true knowledge, which can then be used by decision-makers, becomes particularly unsettled in such circumstances. Writing during the 1970s, Nelkin (1979) suggests that decisions previously considered to be entirely technical – that is wholly within the purview of experts – became steadily loaded with political content. Since then, science and technology has come to occupy a more prominent position within political decision-making – not only by producing new issues for debate, but also by continually reinventing the ability of people to make sense of the world around them. The importance of expert knowledge to the regulatory process means that in order to understand how regulation and standards are produced, consideration must be paid to the formation and social constitution of the scientific knowledge from which experts derive their expertise. This is not to say that scientific knowledge is produced in isolation and then scientists use this to be expert. Instead, and following Jasanoff (2004), the emphasis is upon the co-production of scientific expertise and social order. Scientific experts do possess expertise in a particular field, but this expertise emerges from the conditions in which they project their expertise.

### 2.5.3 Regulatory Cultures and Risk

Thus far, this section has discussed a set of arguments within STS literatures challenging the perception that scientists always exert authoritative claims to knowledge. When science is involved in policy-making, the authority of such claims

becomes further problematised. Moreover, science has become ever more implicated in the process of policy-making. In this regard, policy-making is increasingly concerned with the use of science in the regulation of risks. Some have conceptualised the emergence of risk regulation as the defining articulation of contemporary governing activity (Jasanoff, 1999; Hood *et al*, 2001). According to Jasanoff (2008: 767) “Since the 1970s, the dominant conceptual frame for dealing with the harmful or destabilising effects of technological innovation has been that of risk.” Within this conceptual frame, tools for managing risk have been developed, in particular methods for risk assessment. The application of such tools within policy-making has developed beyond the specific focus of original risk assessment. As Wynne (1992) notes, originally risk assessment tools were designed to be applied to mechanical and (relatively) reducible problems, such as those associated with chemical plants or aircraft technologies. Now, however, such tools have developed into a paradigmatic approach to policy-making. The model of risk analysis is an example of how specific methods for making technical decisions have achieved broader application.

Risk analysis has become an important guiding framework for risk regulation and for the treatment of expertise in the risk regulatory process. In the conventional form risk analysis comprises three elements: risk assessment, risk management and risk communication. The distinction made between the assessment, management and communication of risk denotes a division of expertise. Risk assessment activities comprise scientific work similar to the definition of regulatory science offered by Irwin *et al* (1997) or mandated science as discussed by Salter (1988). Risk management is analogous with the bureaucratic and administrative work undertaken by risk regulators. Risk communication involves the mediated dissemination of information about the risk assessment and risk management process to a wider audience. According to Jasanoff (1987) and Dratwa (2002) the creation of division between science and politics has been achieved in the regulatory process through recourse to risk assessment and risk management as separate activities. In application, these divisions are in no sense fixed and are open to dispute. In the regulatory control systems detailed by Hood *et al* (2001), risk assessment becomes located within information-gathering, while risk management is concerned with standard-setting. Again a division is created between scientific activity and the regulatory process.

Despite contestation over the precautionary principle between the US and the EU (as noted by Goldstein and Carruth (2004) in the case of international trade in food), the risk analysis paradigm is seldom subject to serious challenge. For instance, Dratwa (2002) follows the construction of the precautionary principle in various institutional settings as a result of the European Commission's 'Communication of the Commission on the Precautionary Principle'. He notes that while the precautionary principle is often referred to as existing in tension to the risk analysis paradigm, the concept of precaution itself also follows the division between science and politics. The risk analysis paradigm therefore remains settled. Dratwa suggests that as a result of various drafts of the Communication: "...the precautionary approach is thus part of the risk assessment policy, and indeed of the scientific advice provided by risk assessors, while the precautionary principle is confined to risk management alone." (Dratwa, 2002: 202). Horton (2001) also draws attention to the different use of the terms precautionary principle and precautionary approach. The former is said to be used by the European Commission to emphasise the ability of risk management decisions to override risk assessment. The latter, the precautionary approach, is said to be favoured by the US and involves a greater emphasis in the process of risk assessment as a precautionary activity which will form the basis of risk management decisions. The debate over the demarcation of risk assessment (precautionary approach) and risk management (precautionary principle) challenges understandings of expertise and expert decision-making. In the case of debate over the precautionary principle within the Codex Alimentarius Commission, Dratwa (2002) states that the assertion of the precautionary principle by the European Commission and EU member states – and in particular the introduction of all pertinent factors including socio-economic factors to risk assessment – is significantly shaped by the risk analysis paradigm as defended by the US. As a result, the emphasis upon science-based risk assessment is reasserted. The scope of expertise relevant to risk assessment is thus closed down, restricting the role of some experts to risk management activities which have to be conducted in reference to risk assessment.

The significance of risk as an organising concept for regulation is recognised by Rothstein *et al* (2006). They assert that the concept of risk now pervades regulatory activities and that it does so both quantitatively and qualitatively. The broadened scope of risks falling under the concerns of regulators has resulted in a quantitative increase in

risk regulation. In short, more things are deemed risky and more regulation of these risks is required. Further, there has been an internalisation of risk within risk regulation institutions, producing regulatory institutions not only dealing with risks but also operating defensively against the threats to their own legitimacy produced by ‘failed’ or ‘unsuccessful’ attempts to regulate risks. Regulatory activity therefore not only deals with increasing quantity of social risks, but through this activity must also deal with new risks to the regulatory process itself. Rothstein *et al* (2006) go on to propose three approaches to conceptualising the relationship between risk and regulation: risk society as regulatory society, regulatory society as risk society and risk as an organising concept for decision-making. The first approach is closely related to the notion of the quantitative expansion of risk requiring regulation. This notion places the conceptualisation of a ‘risk society’ at its heart and the growth in risk regulation as a response (Beck, 1992; 1999). New risks emerge in established sectors such as food and in newer technological sectors such as telecommunications. Scientific and technological innovations are viewed as stimuli for these risks, which require new responses in the form of regulatory control systems.

The second mode of analysis identified by Rothstein *et al* (2006) suggests that, rather than the increasing elaboration of risks within society producing heightened regulatory activity, instead changes to the operation of regulatory frameworks have produced an increasing attention to risks. Such an emphasis takes its cues from those writing about the rise of regulatory state (Majone, 1994; Moran, 2003). In this approach to regulation, the production of knowledge about risks, through information-gathering, helps to expand the scope and intensity of regulatory activity to manage risks. And so a cycle is initiated in which knowledge about risks increases through intense information-gathering, which then increases the risks to be managed, necessitating further activity to try and manage these newly identified risks. The third approach is defined by Rothstein *et al* (2006) as: “At its simplest, risk-based governance is about prioritizing activities according to the impact and probability of societal risks, whether for standard-setting or compliance purposes”. Taking these two strands of analysis together, the implication for understanding science and regulation is that regulation is increasingly concerned with managing risks while simultaneously using the notion of risk as a means of organising regulatory activity.

One result of an increasing emphasis upon regulation for the management of risk is the growth in regulatory science. Regulatory science is the funding of scientific activity focused upon providing information for the conduct of regulation. According to Irwin *et al* (1997), regulatory science involves five stages. First, speculative (or basic) research is carried out that may have relevance for the regulatory process and provide new sources of evidence. Second, there is the development and validation of regulatory tests in order to assess possible hazards emerging from new evidence. Third, regulatory compliance testing is undertaken by the relevant industry groups as specified by regulatory agencies. Fourth, investigative problem-solving is pursued to assess the falsifiability of regulatory compliance testing and to reveal whether findings are relevant to risk assessment. Finally, regulatory submission is achieved whereby information can be provided on the risk assessment process to regulators. Regulatory science becomes a generative element of risk regulation, reporting on current risks as mandated by regulators but also identifying and producing new risks. This in turn expands the scope for regulatory activities and following the regulatory control system outlined by Hood *et al* (2001) and requires further information gathering. While the expansion of risk production and regulation is one aspect of risk regulation viewed from the perspective of regulation within governance, a separate problem is the ability of the policy domains in which risk regulation occurs to map onto newly emerging risk problems.

Organisations also face risks in the form of threats to credibility and competency. Such risks are of a different kind to the risks dealt with by the risk analysis paradigm. Organisational risks emerge from attention to the performance of organisations and their ability to meet stated goals and objectives. Regulatory organisations are, for instance, under the increased scrutiny of internal and external audits (Power, 1999). Power *et al* (2009) have explored the importance of reputational risk to the ways in which organisations are configured. Reputational risk is often assessed by external organisations and is conceptualised as product of social interaction. In this way, reputational risk presents a different type of challenge to organisations than that posed by risk analysis.



#### 2.5.4 Regulatory Diffusion and Standard-Setting

The diffusion and harmonisation of regulatory systems frequently occurs via the process of standard-setting. As a form of regulatory activity, standard-setting brings into close proximity and dialogue differentiated regulatory cultures. As Majone (1984: 15), states: “Far from being an almost mechanical process safely relegated to technicians, the setting of health, safety, and environmental standards is in reality a microcosm in which conflicting epistemologies, regulatory philosophies, national traditions, social values, and professional attitudes are faithfully reflected.” The seemingly technical nature of standard-setting means that questions with significant political content can become conceptualised as essentially non-political concerns. Longstanding technical, standard-setting organisations such as the Codex or OIE – with a history located in the production of non-binding, scientific guidelines – have become increasingly entangled with such de-politicisation. De-politicisation, the reconceptualisation of political questions as merely technical, has occurred with the referencing of Codex and OIE standards in WTO agreements. In consequence, trade concerns have been introduced into standard-setting bodies previously only concerned with setting guidance for health regulation.

The interconnection of political and technical concerns and the re-conceptualisation of these concerns as only comprising technical questions are not uncommon. In the agri-food sector, issues presented as only technical frequently have origins in political debate and decisions. Stanziani (2007) demonstrates how the issue of food adulteration was a mobilisation of competing interests, actualised through a debate about levels of contamination and safety. Writing about the French experience of food regulation, he suggests that economic lobbies attempted to make use of the institutions of food regulation to advance market share through new innovations. In this sense food regulation is implicated in the differentiation of the food sector and the marketing of new products. Concerns over public health in this sense are implicated in product differentiation. However, the introduction of organic chemistry into the agri-food sector (along with urbanisation, institutional mediation and internalised markets) significantly unsettled existing notions of competition. Thus claims over quality became an outcome of political and technical negotiation.

The arguments presented by Stanziani (2007) suggest that producing positive law in order to direct the agri-food sector is not possible given the complexity and technical content of the decisions to be taken. Instead food regulation is the outcome of constant negotiations over those characteristics of food which enable differentiation, particularly on the basis of quality and safety. Similarly, the location of Codex and OIE standard-setting within the WTO framework is an attempt to ensure that scientifically informed standards can be produced to guide food production and trade, despite constant negotiations over notions of food quality and safety which enable market differentiation. Despite the claims that Codex and OIE standards have a scientific basis, the instigation and negotiation of these standards are political events with a strong technical dimension. In linking trade concerns with public health concerns through WTO agreements, the configuration detailed by Stanziani has been institutionalised at the intergovernmental level.

The expansion of risk regulation activities prompted by WTO agreements has, according to King and Narlikar (2003), occurred via the steady integration of risk regulation systems between states. They suggest that international organisations have taken on new functions as global risk regulators and in doing so "...have responded by going deep into the regulatory regimes of states, which raises concerns about their accountability and may presage their institutional restructuring." (King and Narlikar, 2003: 338). Deep risk regulation is said to be partly a result of international coordination at the domestic level. Such co-ordination is deemed to be different to previous co-ordination at the intergovernmental level, as deep risk regulation requires active restructuring of domestic regulatory systems. Such restructuring is contrasted with domestic responses to aspirational international objectives. Deep risk regulation involves changes to the means by which individual governments go about risk regulation as opposed to simply obligating them to reach agreed targets. The diffusion and harmonisation of regulatory systems is an important driver of deep risk regulation.

Since the creation of the world trade system, the diffusion of many regulatory systems between countries is occurring in a context of what Majone (2003) terms 'deep integration'. Deep integration involves the convergence of regulatory systems between states and marks a qualitative shift from earlier pre-occupations with the harmonisation of trade policies implemented at national borders e.g. import tariffs. Harmonisation of

regulatory systems in various sectors is occurring through a variety of processes, namely: policy imitation between states, take-up of draft regulations by professional bodies, self-regulation through private standard-setting clubs and international standard-setting organisations (Majone, 2003). These last two activities have become particularly prominent. The growth of regulatory activity both nationally and internationally has had the effect of linking divergent regulatory systems within specific sectors and bringing them into co-operation and competition. The tension between regulatory co-operation and competition has been described by Geradin and McCahery (2004) as regulatory co-opetition. They suggest that the concept of co-opetition captures the differing degrees of co-operation and competition which exists between actors within a regulatory regime. Regulatory co-opetition can occur at different levels, for example intergovernmental regulatory co-opetition refers to the dynamics of competition and cooperation taking place among governments. Intergovernmental regulatory co-opetition can take place on a horizontal, multilateral basis as evidenced in harmonisation activities occurring in, for example, the Codex Alimentarius Commission or the International Labour Organisation. Regulatory co-opetition can also occur vertically, for instance between the European Commission and EU member states. The consequence of regulatory capitalism is an increase in instances of regulatory co-opetition between states in relation to their regulatory systems. In addition extra-governmental regulatory co-opetition can occur between state regulatory bodies and non-governmental actors. The growth of regulatory co-opetition has amounted to an increased velocity of regulatory diffusion, as co-operation and competition between regulatory systems can lead to the diffusion of regulation from one country to another. Similarly, Post (2005) notes the differentiated diffusion of international food standards amongst member governments of the Codex, while Levi-Faur (2005) suggests that regulations have origins in leading countries and are diffused to the rest of the world.

Crucial to the negotiation of standards are experts. According to Jacobsson (2000), those who are involved in the production of standards regard themselves as using 'technical expert knowledge' in the course of standard-setting activities. While the knowledge used in setting standards is often regarded as technical knowledge, this does not mean that the process of standard-setting is a technical process. In fact, the standard-setting process may become highly disputed and protracted due to disagreement between those involved in standard-setting. The technical in these

instances becomes equated with the optimal; that technical experts are optimising experts who are constantly suggesting solutions which provide the best outcomes for society. More sceptically, Jacobsson (2000) suggests that standardisation through standard-setting is problematic because of the importance attached to expertise. He suggests that this can lead to depoliticisation of the standard-setting process, technicalisation of the terms of debate and the emergence of regulation devoid of wider public responsibility. Likewise Busch (2000) has suggested that standards set norms and conventions and in doing so help to configure the behaviour of many actors involved in the governance of the agri-food system. As a result, standards are imbued with moral and ethical judgements which are frequently subsumed within technical procedures.

The relatively incremental nature of standard-setting means that the process is frequently ignored as a significant part of politics, narrowly defined. Yet diffuse systems of expertise are now factors in international re-regulation. Kerwer (2005) suggests that international standards are proliferating as they do not provide 'hard' prescriptions to sovereign states, but instead enact processes of consensus and argumentation. Three main modes of international standard-setting are identified by Kerwer (2005): private standardisation; committee standardisation and organisational standardisation.<sup>15</sup> Private standardisation involves the devising of standards by a private group – such as a firm, professional organisation or consumer group – and the subsequent take-up of these standards by others. Committee standardisation involves standard-setting by transnational committees comprising expert administrators in a given field. Organisational standardisation occurs within an organisation comprising governments as members. In this form of standardisation, standards are agreed by consensus and the government members are expected to enforce the standards at the national level. The dimensions of these modes of standard-setting are shown on the following page in figure 2.3:

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<sup>15</sup> Kerwer (2005) also identifies network standardisation as a possible solution to the accountability problems of committee standardisation. However, for issues of clarity this has been omitted.

	Actors	Addressee	Enforcement	Accountability
<b>Private standardisation</b>	Standard setters, standard users, enforcement agents	Best practice for many	Legal, market exit, evaluation by audit	Low
<b>Committee standardisation</b>	Transnational committee of regulators, private lobbying and consulting	Best practice for public administration	Peer review, market pressure	Medium
<b>Organisational standardisation</b>	Decision making supervised by members	Standards for members	Compulsory for members	High

*Figure 2.3: Dimensions of three modes of international standardisation*  
*(adapted from Kerwer, 2005)*

The modes of standardisation presented by Kerwer (2005) draw attention to the various institutional contexts in which expertise is utilised in international standard-setting. In the organisational mode, input by experts to standard-setting occurs under scrutiny from group members – government delegations in the case of intergovernmental institutions - – who attempt to reach a consensus on the form of a given standard. The definition of a standard used by Kerwer is “voluntary best practice rules”. Yet in the organisational mode of standard-setting, ‘best practice’ does not necessarily capture the coercion that can result from the agreement of a standard. In the case of standards produced in a standard-setting organisation referenced by WTO agreements, the WTO dispute panel will use these standards to determine the outcome of trade disputes. In this way standards, referenced by the WTO agreements, such as the reference to the standards set by the Codex Alimentarius Commission in the SPS and TBT agreements, have been described as invoking a quasi-legal authority (Veggeland and Borgen, 2005). Despite the hybrid coercive and consensual nature of standards, the notion of voluntary conformity does persist in definitions of standards as forms of regulation, as distinct from mandatory directives (Brunsson and Jacobsson, 2000). The coercive yet voluntary nature of standards captures the concerns of Rose (1993) with the ability of apparently

distant and obscure systems of expertise to exert authority, without the need for directives and orders.

Despite the diffusion and harmonisation of regulatory systems, differences amongst national regulatory cultures remains in evidence. It is proposed by Jasanoff (2005) that the conduct of regulation uses particular tools which emerge from cultural contexts and that the tools of regulatory science – such as risk assessments – are conducted within specific cultural contexts which frame the scientific and regulatory process. Accordingly some scientific arguments can be dismissed, or viewed unfavourably, whilst others gain support, even in the absence of certainty or agreement, depending upon regulatory culture. Regulatory cultures, while embedded in national contexts, are not static. Further, in the production of international standards aspects of regulatory cultures are brought into a process of negotiation. This has happened in the case of the food sector and European integration (Cumbers *et al*, 1995). According to Jasanoff (2005) regulatory cultures are composed of a number of assessment criteria which are applied to expert knowledge claims. The criteria include: styles of producing knowledge claims, methods of accountability, demonstration practices for knowledge claims, methods for producing objectivity, the basis upon which expertise is recognised and the visibility of expert bodies. In this sense regulatory cultures are not closed and isolated tribes of experts, though experts may exhibit tribal norms (Campbell, 1979). Instead, the notion of regulatory cultures connects the activities of experts in the regulatory process to different traditions of regulation from which they may be situated. The assessment criteria for knowledge claims are therefore woven into the political process as knowledge is an inherent part of politics.

The assessment of knowledge claims depends in part upon the methods by which knowledge claims are produced. Using examples from biotechnology regulation, Jasanoff (2005) suggests that in the United States knowledge claims have been mainly produced by interest groups, involving inputs from industry, academics and environmental groups. In the UK, the state has played an active role in creating expert credibility through new institutions comprising public servants. In Germany, the regulatory process for biotechnology has occurred through a process of publicly-oriented investigation and then through relatively remote expert systems of decision-making. These approaches can be characterised as interest-based (US), service-based

(UK) and institution-based (Germany). Once knowledge claims have been produced, a set of methods are deployed to test and judge the claims. For instance, knowledge claims must be demonstrated. As Rip (2002) suggests, expertise is formed around demonstrations to an audience. The practices used to demonstrate knowledge claims can vary with regulatory cultures. Again, using Jasanoff's example, in the US socio-technical experiments are most readily utilised as demonstration tools. These comprise public demonstrations of the benefits offered by a technology and invite debate and critique. In the UK, such public demonstrations are less common and instead a relatively remote elite science founded upon empirical observation is dominant. Optimistic claims for technology are more qualified in this regulatory culture. In Germany, demonstration practices involve dialogue between experts based upon an assumption of rationality. As a result demonstration practices are conducted internally within expert groupings.

The testing of knowledge claims can also depend upon the criteria used to recognise expertise. The difficulty of recognising expertise within liberal democracy is that: "...the rules of credibility, unlike the rules of constitutional delegation, are in all modern states almost entirely unwritten. They are cultural properties and as such are a source of cross-cultural variation." (Jasanoff, 2005: 267). In the case of the US, professional qualifications and skills are regarded as the clearest indication of expert credibility. In the UK, expertise is more closely associated with the individual person, particular through a record of public service. Individual personalities are less important indicators of expert credibility in Germany, where experts are made credible through their work within expert institutions (Jasanoff, 2005).

The growth in international policy-making requiring scientific input has implications for the conduct of scientific activity and the production of knowledge claims. However this division between science and policy-making – as suggested by the notion of scientific 'input' – has been challenged from an STS perspective. While the harmonisation and integration of deep risk regulation is creating new dynamics between national and international attempts to govern – so much so that it becomes increasingly problematic to speak of them as distinct realms – comparative policy analyses of risk regulation have shown the persistence of differences between nations (Jasanoff, 2000). Jasanoff (2005: 255) has attributed these differences to the variety of "...institutionalised

practices by which members of a given society test and deploy knowledge claims used as a basis for making collective choices.”

#### 2.5.5 Constructing and Mediating Boundaries

As suggested earlier in this section, the construction of boundaries between science and non-science has been identified by Gieryn (1983) through the notion of boundary work. The active demarcation of boundaries between scientific expert and non-expert can be used to protect realms of activity from questioning. In an international policy-making context, Miller (2004) suggests that boundary work often has the effect of ensuring a Western model of science-based policy-making prevails. The use of science as a category with which to ensure the protection of knowledge claims is a particularly potent strategy if wide inequalities in scientific expertise exist across nations. Moreover, scientific expertise can be mobilised as a quality possessed by some nations and lacking in others. The possibility for discussion to be closed down on the basis of a participant having insufficient scientific expertise thus increases.

The use of boundary work to ensure authority over knowledge claims becomes problematic in instances of scientific uncertainty and policy-making. Despite the tendency of scientists to undertake boundary work (Gieryn, 1983), for those scientists who must advise policy-makers it is not easy to restrict debate in this way. Rather an acknowledgement of scientific uncertainty is required. According to Shackley and Wynne (1996: 278) “when the consequences of attributing scientific uncertainty are so significant to a range of policy actors, the scientific community no longer has full autonomy to decide whether and how scientific uncertainty is presented to outsiders.” As a result, scientific advisors must negotiate uncertainty amongst a diverse range of actors and interests.

The attention of Shackley and Wynne (1996) is upon the heterogeneity of understandings of uncertainty which permeate a policy-making process. In order to conceptualise the methods by which diverse groups deal with shared uncertainty, they developed the notion of boundary-ordering devices. In doing so they draw upon the work of Star and Griesemer (1989) and in particular their concept of the boundary object. For Star and Greisemer (1989), scientific work often requires co-operation



between actors from different social worlds, though they do not necessarily have to be able to establish a consensus over the issue in question. They regard boundary objects as particularly crucial entities for managing co-operation. Boundary objects are defined as:

objects which are plastic enough to adapt to local needs and the constraints of the several parties employing them, yet robust enough to maintain a common identity across sites. They are weakly structured in common use, and become strongly structured in individual-site use. These objects may be abstract or concrete. They have different meaning in different social worlds but their structure is common enough to more than one world to make them recognisable, a means of translation. The creation and management of boundary objects is a key process in developing and maintaining coherence across intersecting social worlds.

(Star and Greisemer, 1989: 393)

The emphasis of Star and Greisemer (1989) is upon boundary objects acting as common entities for multiple actors, which are capable of being translated by those actors in divergent ways. While the notion of boundary work seeks to draw attention to the active construction of boundaries between expert and non-expert groups, the concept of boundary objects pays attention to the entities which are used to create coherency and co-operation between groups with divergent interests. Crucially, boundary objects can be adapted to the needs of a group, while retaining enough coherency to remain useful to others. In this way, boundary objects mediate boundaries.

In detailing the concept of boundary objects, Star and Greisemer (1989) suggest four types of boundary objects: repositories, ideal types, coincident boundaries and standardised forms. Repositories are collections of objects organised into a standardised form, therefore allowing multiple uses. Ideal types are abstract descriptions and are particularly adaptable due to their vagueness. Coincident boundaries refers to boundary object which, while have shared boundaries, have different internal compositions. Finally, standardised forms are methods of communication across work groups and therefore retain diverse information in a recognised configuration.

The concept of boundary objects as proposed by Star and Griesemer (1989) suggests that objects can possess both flexibility and coherence. As a result they can be subject to interpretation while also providing a basis for shared actions. A comparable concept is that of immutable mobiles (Latour, 1987). Immutable mobiles are those objects and devices containing information which are stabilised over time and then are able to travel and act upon others. For Latour (1987), facts and objects – immutable mobiles – are constructed by fact-builders and object-builders. The connection between fact-builders and object-builders is one which links science and technology. Latour asserts that:

The problem of the builder of the ‘fact’ [scientists] is the same as that of the builder of ‘objects’ [engineer/technologist]: how to convince others, how to control behaviour, how to gather sufficient resources in one place, how to have a claim or the object spread out in time and space.

(Latour, 1987: 131)

The work that boundary objects or immutable mobiles can do – that is the effects they can have over distance – emerges from their construction by fact-builders and object-builders alike.

The differentiated concept of boundary objects retains a core concern with the adaptability of boundary objects. According to Jasanoff (2005: 27) boundary objects are “repositories of multiple meanings” which cannot be easily reduced to a single static form. Similarly Mol (2006) suggests that boundary objects remain ‘fuzzy’ in order to allow for tensions between groups who share claims to the object. Thus, boundary objects have to remain in some sense definite (or else they are no longer objects) while remaining amenable to interpretation by groups interested in their form. However, it is the durability of boundary objects which, according to Shackley and Wynne (1996), stands in contrast to the uncertainty discourse of scientific advisers. In the delivery of scientific advice, they suggest that short-term constructions are used rather than long-term, durable forms. In paying attention to the temporary discourse used in such circumstances, they propose the term boundary-ordering devices to describe the methods used to cross boundaries and allow for co-operation in dealing with uncertainty. The approach of Shackley and Wynne (1996) represents a conceptual move which integrates the notions of boundary work (with a focus upon constructed differences between groups) and boundary objects (those objects which enable co-

operation). Such an approach has been discussed by Waterton and Wynne (2004) in understanding regulation as a boundary object subject to intense interpretive work. Demortain (2007) has also drawn upon the concept of boundary objects to analyse the development of regulatory concepts used in the construction of the Hazard Analysis Critical Control Point System (HACCP).

While the concept of boundary objects has been used and adapted, it has also been criticised for placing too great an emphasis upon co-operation between groups. According to Gomart and Hennion (1999), the concept of boundary objects is myopic, as the boundary object passes between groups with minimal levels of difference emphasised. They suggest that often groups interact on the basis of precise differences over an object, rather than on the basis of a blurred artefact. Conversely, in a case-study of the controversy over advice on cholesterol intake which employs the concept of boundary objects, Garrety (1997: 755) suggests that, in areas of persistent controversy, science is never settled and so the designation of the natural remains elusive. She asserts that the boundary object analysis invites discussion of differences between groups, while actor-network approaches are concerned only with the elaboration of a network of associations through enrolment. From the actor-network perspective, enrolment, according to Callon and Law (1982), involves sets of actors exciting or interesting other sets of actors in their way of knowing. In this way, actors can become enrolled in the schemes of authors through various methods, such as the composition of a research paper or the marketing of a technological artefact. The concern of this mode of analysis is “to discover how actors enrol one another, and why it is that some succeed whereas others do not.” (Callon and Law, 1982: 621). The concept of boundary objects also uses the terminology of enrolment, though with a different emphasis. According to Fujimura (1992), actor-network approaches pay close attention to the stabilisation of ‘facts’ through enrolment and translation, while the boundary objects concept is used to illuminate different, local viewpoints on a shared object of meaning.

## 2.6 Conclusions

In this chapter a number of important concepts have been introduced which will be used in the remainder of study. Firstly, the idea of an agri-food system suggests that

seemingly discrete domains of production or regulation are connected. The production, manufacture and consumption of food products is heavily mediated by diverse systems of control, which are increasingly responding to scientific and technological developments. The consequences of such an assertion are that, in order to produce an adequate understanding of the regulation of the agri-food system, it is necessary to set-out adequate concepts for interrogating the relationship between science and policy-making.

One concept which claims to address this question, particularly from an international perspective, is that of epistemic communities. However, despite the promise such a concept offers in terms of understanding the important role of scientific debate in international policy-making in technical domains, the concept has some significant deficiencies. In particular, and as detailed in Section 2.4, the concept draws upon a naïve notion of scientific knowledge. In response, the final substantive section details a number of concepts developed in the sociology of science and technology and the risk regulation literatures. These concepts provide a more critical perspective on the contribution of science to international policy-making and suggest means by which such a contribution can be analysed.

## Chapter Three – Producing the Case-study

### 3.1 Introduction

In order to analyse how the international food standard-setting process is conducted – that is, to understand the methods and events by which international food standards are formulated and agreed – the study employs an in-depth case-study approach. The case-study concerns the successful attempt to agree an international definition of dietary fibre as part of a Codex standard ‘Guidelines for Use of Nutrition and Health Claims’ (Codex, 1997). Therefore, the identification of a case-study was related to the standard-setting activities being conducted in the Codex Alimentarius Commission (the organisation hereafter referred to as the Codex) during the period of study (September 2006 – September 2009). Further, the case in question was a Codex standard, or more accurately a component of a Codex standard. Some of the processes involved in the selection of this case-study are detailed in Chapter Four, as they are closely associated with the conduct of the research and subsequent analysis.

This Chapter deals with two closely related processes which enabled the production of the case-study. In Section 3.2, the delineation of the case-study is explained. Firstly, the origins of the Codex are briefly detailed. Here, the transition of the Codex from an informal institution focusing upon best practice to an institution setting standards referenced by international trade agreements is set out. Secondly, the Codex organisational structure and processes for standard-setting are discussed. Both have important consequences for identifying the case-study presented in Chapters Four, Five and Six. In particular, three aspects are explored: the organisation of Codex committees, the risk analysis framework and the procedure for elaborating standards. The section not only discusses the Codex as an organisation, but provides an important examination of the institutional environment in which the case-study was developed.

Section 3.3 deals with methodology. The aim of this section is to provide an account of methods used to conduct the study and to provide a coherent rationale for their application. In order to demonstrate how the study developed, the section is structured chronologically. The research methods used – interviewing, document analysis and

observation - are discussed in relation to their application in the study. As a result the section discusses the practical relevancy of the research methods. In particular, it is argued that the case-study method is appropriate to an investigation which seeks to analyse the process of standard-setting, given that this approach provides highly contextualised knowledge.

### 3.2 The Codex Alimentarius Commission as a Case-Study

It has been argued in Chapter One that the enlargement of international trade regulation into new domains has had important implications for global governance. International organisations, previously considered to be rather unremarkable in their activities, are now assigned responsibilities which have important economic, political and ethical implications. The Codex, as one of these organisations, has been charged with facilitating the agreement of international food standards, as referenced by the WTO. Due to the new status of standards agreed in the Codex, member governments have a heightened interest in the process of international food standard-setting.

The initial scope of this study took the new political remit of international trade regulation as a starting point. The early aim was to identify suitable institutional arenas – implicated to the WTO regime – in which international agreements pertaining to food and agriculture were being negotiated. A suite of WTO agreements came into force in 1995 with important implications for the agri-food system. As a result of this initial investigation into the expansion of the world trade regulation, the study presented here could have been concerned with other affected areas of the agri-food system. For example, the negotiation of tariff barrier reductions for animal products or the agreement of international plant variety protection policies were all considered as possible topics for study. Indeed, previous work had considered the case of intellectual property rights and plant varieties (see Lee, 2007). Instead, the decision was taken to focus upon the international policy domain covering food product standards. Little, if any, detailed, empirically informed social science has been conducted on this process. Therefore, the Codex, as the most prominent intergovernmental institution in which such policies are agreed, became the focus of further empirical study.

In this section, the origins, organisation and operation of the Codex are detailed in order to demonstrate how the case-study emerged. The institutional configuration of the Codex has an important influence upon the delineation of a process-oriented case-study. If attention is to be paid to the process by which standards are agreed, then an understanding of the context in which agreement occurs is required and so it is necessary to understand how the Codex functions. In this regard, the discussion of methodological issues (covered in Section 3.3) – which are those issues concerning the actions taken to conduct the empirical investigation based upon conceptual premises - requires an appreciation of the Codex as an institution. Therefore, it is appropriate to discuss the configuration of the standard-setting process together with the means by which the case-study was produced.

As discussed in Chapter One, the Codex is an intergovernmental organisation which oversees the implementation of the Joint FAO/WHO Food Standards Programme on behalf of the FAO and WHO. The standard-setting process consists primarily of negotiations between member governments of the Codex<sup>16</sup>, although observer groups<sup>17</sup> can also contribute comments and make interventions. However, the origins of the Codex are found outside of the UN system, with the formation of the Codex Alimentarius Europaeus in 1958. According to Randell (1995) the Codex emerged from this initial work within Europe to establish an international food code. The notion of a European organisation devoted to the production of food standards attracted attention from non-members, notably the US. In response, in 1962 the intergovernmental Codex Alimentarius Commission was created as a joint agency of the FAO/WHO. Twenty seven member governments participated in the first session of the Commission in 1963<sup>18</sup>.

The Codex began to undergo institutional change during the late 1980s. Before the SPS and TBT agreements were finalised in 1994, work was taking place to reconfigure the Codex in order to address the demands of integration into the trade system. In March 1991, the FAO/WHO Conference on Food Standards, Chemicals in Food and Food

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<sup>16</sup> At the time of writing there were 180 member governments and 1 member organisation (the European Community).

<sup>17</sup> Observer groups are those recognised by the FAO/WHO and comprise industry and consumer groups who have an interest in international food standards.

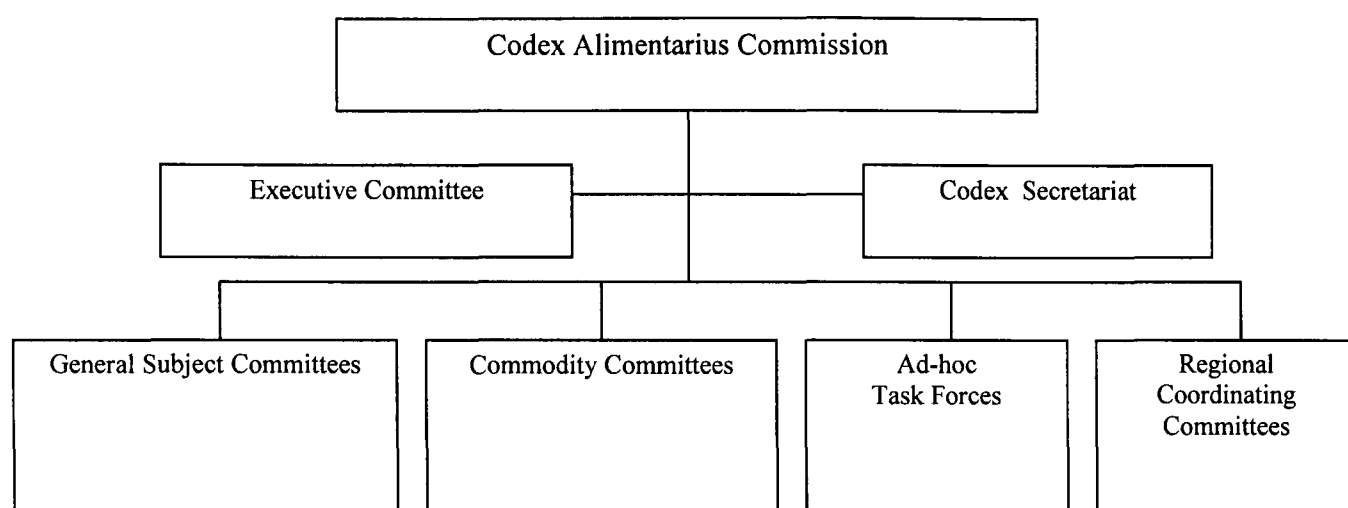
<sup>18</sup> Australia, Austria, Belgium, Canada, Denmark, France, Fed Rep of Germany, Greece, India, Israel, Italy, Luxembourg, Netherlands, New Zealand, Norway, Pakistan, Poland, Portugal, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, United Kingdom, United States and Yugoslavia.

Trade was held in co-operation with the General Agreement on Tariffs and Trade (GATT). The main outcomes of this conference were proposals to reduce the detail contained in many Codex standards, to review the scientific basis of Codex standards (given the need under the proposed GATT agreements for countries deviating from Codex standards to provide scientific evidence for doing so), making more explicit the methods used for risk assessment in standard-setting and increasing the participation of developing countries in the Codex (McNally, 1991). While the TBT and SPS agreements came into force from the 1 January 1995, the effects of the run-up to the Uruguay Round were felt from 1991 onwards. In the Codex, disputes between EU member states and the 'Quad' or 'Cairns' Group (comprising the US, Canada, Australia and New Zealand) were occurring. As Jukes (2000) notes, tensions over the use of hormones in cattle for beef and milk production were intensified in the Codex during the early 1990s.

The Codex post-WTO deals with an increasing array of complex issues, but operates through a distinctive institutional configuration. In this section, four aspects of the operation of the Codex will be dealt with: the organisational structure, the risk analysis framework, the procedure for elaborating standards and the facilitation of consensus. Each aspect contributes to the functioning of the Codex and so must be understood in order to produce a case-study of the standard-setting process. In particular, the emphasis upon contextualised knowledge in the case-study approach demands that the research methodology considers the institutional environments. The importance of context to the case-study approach will be examined in Section 3.3. For the remainder of this section, the functioning of the Codex will be considered in greater detail.

The organisational structure of the Codex has developed to account for the diversity of issues dealt with by the Codex (including pesticide residues, food labelling, milk and milk products and methods of analysis) and, increasingly, to provide strategic direction work management to standard-setting. The organisational structure of the Codex is illustrated on the following page in basic form:





*Figure 3.1: Basic organisational structure of the Codex*

At the top of this organisational hierarchy sits the Codex Alimentarius Commission (hereafter referred to as the Codex Commission), which operates as the highest level meeting of the organisation (the organisation is referred to simply as the Codex (see Acronyms and Abbreviations)). In the Codex Commission, matters from all other Codex committees are addressed, final Codex standards adopted and wider organisational issues discussed. The Codex Commission meets annually, the venue alternating between FAO and WHO headquarters. Agenda items are agreed in advance and a significant amount of time is spent adopting Codex standards which have been agreed in draft form in other Codex committees. In this way the Codex Commission acts as the final place for discussion before Codex standards are adopted, although revisiting debates which have taken place in previous committees is strongly discouraged. The operation of the meeting is steered by the Chairperson and vice-Chairs (who are elected by Codex member governments on a regional basis). In addition, the Codex secretariat fulfils a vital role in the functioning of any meeting through the preparation of documents. In particular, the Codex secretary is seated alongside the Chairperson and, with assistance from other members of the secretariat, advises the Chair and makes interventions in the meeting. The secretariat provide an institutional memory and are adept at recalling the origins of contemporary discussions in Codex sessions and in ensuring the discussion fall within the prescriptions of the Codex ‘Rules of Procedure’. The picture shown in figure 3.2 – taken during the 2007

meeting of the Commission - illustrates how the meeting is spatially organised, with the Chairperson and secretariat seated in front of the member government delegations.<sup>19</sup>



*Figure 3.2: Meeting of the Codex Alimentarius Commission in 2007 (R P Lee)*

In the organisational structure of the Codex (see figure 3.1), the Codex Commission and the Codex Secretariat are placed towards the top of the hierarchy. Also placed in a prominent position is the Executive Committee of the Codex Alimentarius Commission (Codex Executive Committee). The Codex Executive Committee is the elected, executive organ of the Codex and comprises member government delegates who have been elected as Chairperson, vice-Chairpersons and regional representatives.<sup>20</sup> According to 18<sup>th</sup> Procedural Manual of the Codex, a particular function of the Codex Executive Committee is to:

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<sup>19</sup> Note the session in this picture has been adjourned for a coffee-break. During the sessions all participants would normally be seated.

<sup>20</sup> Codex regions are: Europe, Africa, Near East, Asia, Latin America and the Caribbean, North America and South West Pacific.

make proposals to the Commission regarding general orientation, strategic planning, and programming of the work of the Commission, study special problems and shall assist in the management of the Commission's programme of standards development, namely by conducting a critical review of proposals to undertake work and monitoring the progress of standards development.

A criticism of the Codex has been that the standard-setting process takes too long to complete and that too much standard-setting work is being undertaken. Given the strategic and programming responsibilities of the Codex Executive Committee, the grouping has found itself subject to greater scrutiny. According to one government delegate:

...the executive committee used to be like a figure head, they didn't actually do a lot. They would have a lot of discussion but there would not be a lot of recommendations that would come out of the Executive Committee. Whereas now a lot of these things are discussed in the Executive Committee, the executive committee makes the decision then the [Codex] Commission just endorses it, which is much better use of time and much more efficient.

(Interview, 5<sup>th</sup> July 2007)

An evaluation of the Codex carried out in 2002 proposed that the Codex Executive Committee be granted more powers in the form of an Executive Board and Standards Management Committee (Traill *et al*, 2002). However, concerns over the transparency, efficiency and inclusiveness of such a change were made by some member governments. Instead, it was agreed that in order to speed up the standard-setting process, the Codex Commission should meet annually (whereas previously it met every two years) and the Codex Executive Committee should meet biannually (whereas previously it met annually). These arrangements remain current.

Generally, discussions concerning scientific advice do not take place in the Codex Commission or Codex Executive Committee. Instead, a range of intergovernmental subject committees – often termed subsidiary committees – exist to deal with particular topics requiring food standards. In figure 3.1, these committees are classified as general subject committees (setting cross-cutting standards), commodity committees (setting commodity specific standards), ad-hoc task forces (forming around particular issues) and regional co-ordinating committees. As of 2009, there were fourteen active committees meeting annually to deal with technical discussions, and one ad-hoc task

force.<sup>21</sup> In addition, the Codex Committee on General Principles (Codex Principles Committee) meets every year to agree amendments and changes to the working procedures of the Codex.

Thus far this section has provided an overview of the organisational structure of the Codex. Such an overview is necessary in order to contextualise the production of the case-study discussed in more detail in Section 3.3. The Codex is a complex organisation, dealing with highly scientific and technical negotiations over food standards. In order to manage such discussions, the organisation comprises specialist committees dealing with specific questions or standards. The decisions reached by these committees are then referred to other committees and eventually to the Codex Commission for adoption. In order to impress a general mode of working upon and between these specialist committees, the Codex utilises a set of general procedures (agreed and amended in the Codex Principles Committee). These procedures are crucial to the process of standard-setting and are published in the procedural manual of the Codex, which is now in its eighteenth edition.

The procedures of the Codex address – amongst other considerations – working principles for risk analysis. The working principles for risk analysis are of particular importance to the standard-setting process, as they provide a framework for the relationship between scientific advice and the agreement of a Codex standard. The risk analysis framework is formally divided between risk assessment, risk management and risk communication. A fourth element, risk assessment policy, is to be incorporated within risk management. The following definitions of these terms are applied within the Codex:

**Risk Assessment:** A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Management:** The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk

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<sup>21</sup> Comprising an Ad-hoc Intergovernmental Task Force on Antimicrobial Resistance and standing Codex Committees on Contaminants in Foods, Fats and Oils, Fish and Fishery Products, Food Additives, Food Hygiene, Food Import and Export Inspection and Certification Systems, Food Labelling, Fresh Fruits and Vegetables, Methods of Sampling and Analysis, Milk and Milk Products, Nutrition and Foods for Special Dietary Uses, Pesticide Residues, Processed Fruit and Vegetables and Residues of Veterinary Drugs in Food.



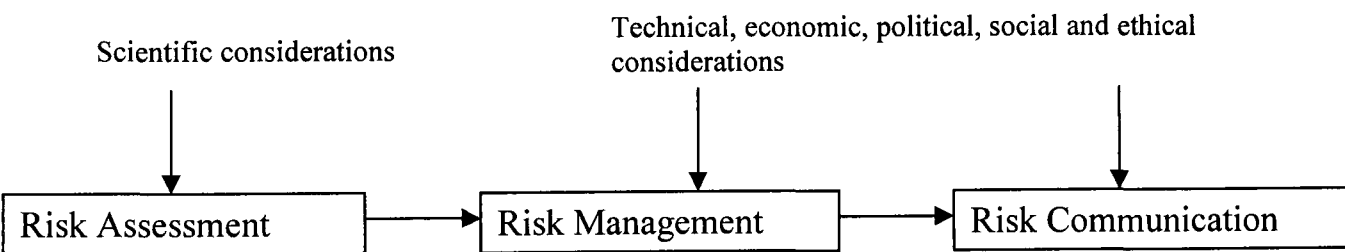
assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**Risk Communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**Risk Assessment Policy:** Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

(Codex, 2007a)

In the procedures of the Codex, member government delegates, who negotiate standards within Codex committees, are defined as risk managers who have responsibility for risk management (Codex, 2007a). Risk management activities take place in the subsidiary committees mentioned above. In order to proceed with standard-setting, risk managers frequently rely on scientific advice. Scientific inputs into the standard-setting process are termed risk assessment. Codex committees, performing risk management functions, take scientific advice from groups which exist outside of the organisational structure presented in figure 3.1. The final element of the risk analysis framework – risk communication – involves ensuring that all information is available for interested parties and that the standard-setting process proceeds with full transparency. The risk analysis framework of the Codex can be represented as:

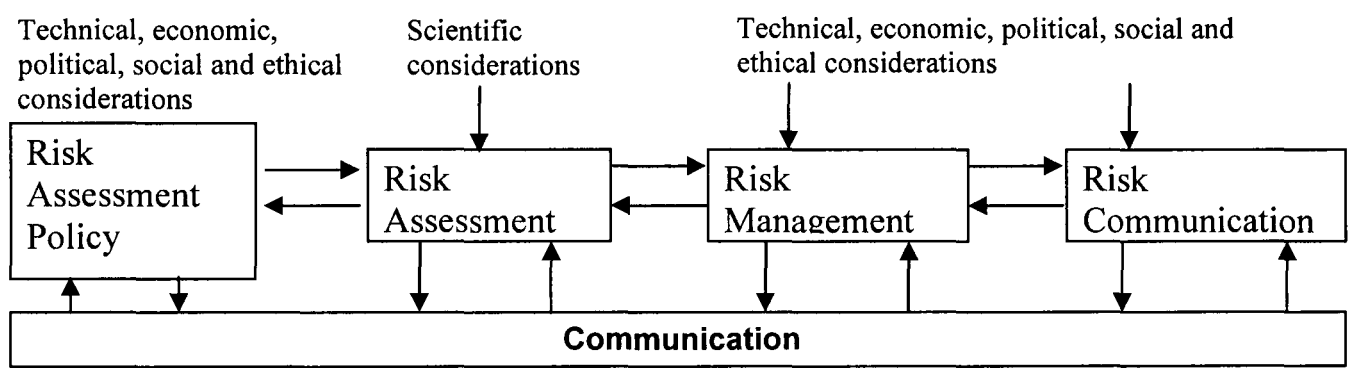


*Figure 3.3: Codex pre-2003 risk analysis framework  
(Derived from Millstone, 2009: 626)*

In this illustration of the risk analysis framework, scientific considerations are confined to risk assessment activities, while technical, economic, political, social and ethical

considerations are made within risk management and risk communication. Scientific advice (risk assessment) is often requested by Codex committees (risk management) in order to set standards. In 2003, the Codex adopted a new element into the risk management function of the risk analysis framework: risk assessment policy. According to the Codex procedural manual: “Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.” (Codex, 2008e: 76)

The inclusion of risk assessment policy as a new element of risk management has, potentially, important consequences for the way in which standard-setting is conducted in the Codex. In contrast to the early model of risk analysis, the new model can be depicted as follows:



*Figure 3.4: Codex post-2003 risk analysis framework  
(Derived from Millstone, 2009: 628)*

According to Millstone (2009), since 2003 the Codex procedures have been formally structured around a ‘co-evolutionary’ model of standard-setting, a model which incorporates risk assessment policy in order to allow for discussion amongst risk managers and risk assessors before risk assessment is undertaken. In addition, specific provisions on risk assessment have been proposed. For instance the Codex Nutrition Committee has agreed ‘Draft Nutritional Risk Analysis Principles and Guidelines’, which were adopted by the Codex Commission in July 2009.

The nutritional risk analysis principles cover the provision of scientific advice to the Nutrition Committee, stating that:

Nutritional risk analysis comprises three components: risk assessment, risk management and risk communication. Particular emphasis is given to an initial step of Problem Formulation as a key preliminary risk management activity.

(Codex, 2009)

Therefore, the proposed draft principles state that a process of problem formulation should be undertaken prior to any risk assessment. Problem formulation is deemed important in that “it fosters interactions between risk managers and risk assessors to help ensure common understanding of the problem and the purpose of the risk assessment.” (Codex, 2009), signifying an explicit recognition that risk assessment should not take place in isolation from risk management. By incorporating risk assessment policy within risk management, the risk analysis framework now recognises that risk assessment (the provision of scientific advice) is initiated on a strategic basis. Risk assessment does not occur without the terms of the assessment being defined in advance. Therefore, risk assessment policy makes this element of standard-setting an overt part of risk management.

As can be seen from the development of the Codex risk analysis framework to include risk assessment policy, Codex procedures have potentially far-reaching effects throughout the organisation. The aim of this section has been to demonstrate the relevancy of the Codex institutional environment to the production of a case-study. In this respect, the risk analysis framework is an important factor, given the prominent position it offers to scientific evidence and advice in the standard-setting process. In considering a case-study of this process, the formulation and articulation of scientific evidence and advice becomes a critical area of investigation. Two other elements of the Codex process are considered in the remainder of this section: the procedure for standards elaboration and the formation of consensus. Both these elements have important implication for the agreement of international food standards.

While the risk analysis framework provides a basis for the relationship between scientific advice and standard-setting, a procedure also exists for the elaboration of Codex standards, termed the ‘Uniform Procedure for Standards Elaboration’ (hereafter the uniform procedure). Following the uniform procedure, Codex standards are advanced from a proposed draft standard initiated by the Secretariat, through to draft versions subject to comment and discussion by member governments and observer groups, and finally to an adopted standard in the Codex Commission. The procedure comprises eight steps. At Step One a decision is taken in the Commission or subsidiary committee to undertake work on a standard in response to a Codex Executive Committee critical review. Once agreed, Step Two requires the production of an initial draft standard, which, at Step Three, is subject to comments by member governments and observer groups. The comments are considered in the relevant committee at Step Four and amendments made to the standard as agreed. The amended standard can be sent to the Codex Executive Committee at Step Five with a view to adoption (in particular if following the accelerated procedure). If further discussion is needed, the Secretariat return the draft standard for further discussion at Step Six. At Step Seven, further amendments to the draft standard can be made. Finally, when Step Eight is reached, the draft standard is sent through to the Codex Commission for adoption. It is possible, following this procedure, for the draft standard to circulate between committees, if further discussion is required. For instance, a standard may move between Step Six and Step Seven.

So far, three important elements of the Codex have been discussed: the hierarchical organisation of committees, the risk analysis framework and the uniform procedure for elaborating standards. The agreement of a Codex standard is guided by all of these elements, but is brought to a conclusion by the establishment of consensus over the form of the draft standard. Consensus is not strictly defined in the Codex; facilitating consensus is a responsibility of the relevant committee Chairperson. The successful facilitation of consensus should negate the use of voting to agree or reject a Codex standard. Overall, the establishment of consensus is promoted not only by the actions of the Chairperson, but by the procedures described above. There is a strong impetus to formulate an agreement over the final draft of a Codex standard.



By providing a detailed discussion of the operation of the Codex, this section has aimed to provide a context to Section 3.3, which is concerned with methodology. The section has not only given an account of scoping activities, but has detailed important aspects of the operation of the Codex. Scoping the parameters of research is an essential activity, especially when using a case-study approach to study a complex institution. By detailing the structure and function of the Codex, it is possible to appreciate the myriad of potential case-studies located within broader case-studies. Becker (1992) recognises that it is common to find cases within cases and so even a single case-study comprises units of investigation. The implications of the case-study approach will be addressed in the following section.

### 3.3 Methodology

The previous section discussed the origins of the Codex, the structure of the organisation and the procedures by which food standards are set. Understanding how the Codex operates was an important part of developing the case-study. This section details the actions taken to focus and conduct the study, in order to elucidate the research methodology. In this sense, methodology is more than the research methods. As Tuchman (1994) notes, the term methodology applies not only to the use of a specific method of research, but also to the epistemological implications of specific methods. These implications are addressed through a detailed account of the research process. In particular, the practical implications of research methods for the production of the case-study are considered. Given that the focus of the study is upon the standard-setting process, a contextualised discussion of methodology is necessary. Further, the contextualised nature of knowledge produced in the case-study is central to the investigation.

The importance of contextualised knowledge to social science investigation has been considered by Flyvberg (2004: 425) who suggests that the “force of example” is often underestimated. He argues that context-dependent knowledge can be achieved by the use of case-study. From this perspective, a preoccupation with generalisation is not considered to be helpful and focus should instead be placed upon the detail which can only be revealed through the narrative of specific cases. The context-dependent

approach to social science is adopted in this study. The implication of this approach is that methodology is more than an activity to gather data in order to produce generalisations about social phenomena. Instead, such empirical work cannot be separated from the case-study. Moreover, both are interlinked to the theoretical work (as discussed in Chapter Two) and, importantly, helps to conceptualise the events subject to analysis. In short, a case is studied on the basis that the methodology has material consequences for the way a case-study is produced. A case-study therefore involves practical, context-dependent knowledge which is produced, in part, by the activities of the researcher. However, such implications of the case-study approach does not mean that the broader ramifications of a case-study should be ignored, or that conceptual ideas cannot be tested using a case-study.

The use of a case-study approach has been considered by Odell (2001). He identifies five kinds of single case-study: the disciplined interpretive, the hypothesis-generating, the least likely (theory confirming), the most likely (theory informing) and the deviant case-study. The disciplined interpretive case-study closely resembles the case-study approach adopted in this thesis, in that it is focused upon a particularly controversial standard-setting process which was brought to resolution. However, as Odell recognises, virtually all case-study approaches are concerned with the interpretation and documentation of dynamic processes. Whether or not they are hypothesis-generating cannot be determined until the study has been analysed and discussed. In terms of theory confirmation (through a least likely case-study) or information (through a most likely case-study), this study deals with the process of agreeing a controversial standard and proposes that authoritative knowledge claims are difficult to establish in such circumstances. It most closely corresponds to a theory confirmation case-study, in that should authoritative knowledge claims settle the process of standard-setting, then the concept of epistemic communities would have validity. While the case-study approach is exploratory, it also represents an instance of theory confirmation (or lack of). As Flyvberg (2004) suggests, such an emphasis upon falsification is an important value of the single case-study approach. He outlines a number of similar approaches to case-study selection, grouped under the classification of information-oriented selection. Of primary importance to Flyvberg is the narrative quality of the single case-study approach. By producing context-dependent analysis of process, the single case-study can provide a rich variety of findings.

The importance of developing in-depth analysis of processes is central to the methodology of this study. As detailed in Chapter One, the research questions were primarily concerned with the process of standard-setting. However, a period of research scoping was necessary to arrive at the specifics of the research questions. Conducting initial work on the Codex proved essential in order to consider possible directions for the research. Scoping activities were centred upon the 30<sup>th</sup> meeting of the Codex Alimentarius Commission, held in July 2007 at the FAO Headquarters in Rome. Prior to the meeting of the Codex Commission, I conducted a telephone interview with a civil servant at the UK Food Standards Agency (FSA) and as a result was invited to attend the UK Codex Contact Meeting in June 2007. Here, further contacts were made with regulators, industry and consumer representatives who had an interest in the production of Codex standards. The meeting also gave me a sense of how the Codex operates, for instance National Codex Contacts Meetings are scheduled to be held in all Codex member countries in order to facilitate input into the standard-setting process. After this meeting, I held a semi-structured interview with the same civil servant in order to address questions which had emerged.

One month later, I attended the 30<sup>th</sup> Session of the Codex Alimentarius Commission at the headquarters of the FAO as a public observer. Being a public observer grants access to the conduct of the meeting, but observers are expected to keep to those areas designated for the public. As discussed in the previous section, the Codex Commission is situated at the head of the Codex committee hierarchy and is the arena in which Codex standards are adopted and strategic issues are discussed. I soon realised that this would be a very busy meeting, conducted over five days and with a large agenda. At this point I was still unsure about how the case-study would be constructed and the precise focus of the research. However, the broad scope of the meeting gave me an indication of the diversity and complexity of issues dealt with the Codex, and that focusing my research would be an essential next step. I conducted some scoping interviews with government delegates and addressed two issues in particular: the role of the Codex Executive Committee in the streamlining of Codex standard-setting and the role of the Codex Trust Fund in supporting participation in the Codex process. Both issues were discussed in the Committee and seemed to have important strategic implications for standard-setting in Codex. In addition, a number of draft standards

which had been sent for adoption raised interesting responses amongst member governments. For example, a standard covering emmenthal cheese produced a vote, largely the consequence of interventions by the delegation of Switzerland who were unhappy the country of origin was not recognised in the standard. As detailed in the previous section, the Codex procedure attempts to ensure that standards are agreed on the basis of consensus, and so this incident raised questions about the standard-setting process. In general, the observations I made gave me a stronger sense of how the Codex operates and how the procedures are implemented by the Chairperson and secretariat.

On returning from the Commission meeting I had a large set of notes and documents to analyse. The next task was to focus the research upon a particular aspect of the Codex. I needed to produce a case-study – or set of case-studies – within the Codex. One approach I considered was to conduct a comparative analysis of the standard-setting process for three or four Codex standards. This would involve creating a comparative scheme by which the standards could be compared. Observing the Commission meeting had revealed a number of Codex standards could be used as case-studies within such an approach.

In considering a comparative approach I came up against the two most pressing concerns in research design: time and resources. Codex standard-setting takes place in committees situated across the world. For instance, China hosts the Committee on Pesticide Residues, while Germany hosts the Nutrition Committee and Mexico hosts the Committee on Fresh Fruits and Vegetables. Conducting a comparative study of Codex standards across different Codex committees would require a considerable amount of funding for flights and accommodation. In terms of time constraints two factors were important. Firstly, the Codex standard-setting process is sequenced: certain committees meet at set times. This co-ordination is allied to the second, and more pressing problem; the amount of time required to become competent on the technical detail of each standard and the operation of each committee. Given that Codex committees meet at set intervals, I had little time to become sufficiently skilled in the substantive discussions of diverse standards and to consider questions arising from the process, let alone construct interview guides and arrange interviews. In short, I deemed that the attempt to conduct a comparative analysis across Codex committees – while

undoubtedly having considerable merit – was unrealistic given the time and resource constraints.

The delineation of a case-study within the Nutrition Committee emerged from discussions with a number of individuals, who offered insights into emerging issues. These individuals could be likened to research informants, in the sense used by Rabinow (2007). The use of the term informant implies a specific role for the research participant, rather than referring to any individual who might respond to a research question (the sense used by Campbell (1955/1969)). A good research informant is often someone who operates as a “technician of general ideas” (Rabinow, 2007: 48). The technician of general ideas occupies a position between local events and global significance. They play an important role in the research trajectory, not by participating in interviews (though they may do this also), but by providing hints, tips and clues as to where interesting events might be taking place. In this instance, such technicians had knowledge in an area of Codex activity I was considering making an object of study. As such, the Nutrition Committee meeting was described as a good opportunity to see the process in action. This committee had grappled with a contentious standard over infant formula for many years, but now had turned its attention to new standards and the resolution of other longstanding ones. In particular, discussions were to be held over standards concerning dietary fibre and the scientific substantiation of health claims. Both these standards were reaching important stages in the Codex process. From this point onwards I began to refine the case-study, focusing less upon developing a comparative study of several Codex standards or the conduct of strategic decision-making, and instead concentrated on the standard-setting process within the Nutrition Committee in November 2007. The observations of this meeting are analysed fully in Chapter Four.

The research became focused upon conducting an analysis of the standard-setting process in the Nutrition Committee for one, or perhaps two standards, and so I began to pay more attention to the specific standards to be discussed at the meeting. Two standards in particular seemed interesting: the scientific substantiation of health claims and the definition of dietary fibre. A conversation with a nutrition scientist at Newcastle University provided a background to these debates and also produced contacts at the International Life Sciences Institute (ILSI). Again, further discussion of

this is taken up in Chapter Four. Prior to attending the Nutrition committee, I also contacted a number of government regulators – identified from their attendance at previous meetings of the Nutrition Committee – to arrange interviews around the meeting, with varying degrees of success. I considered interviews – or more precisely in-depth interviews with guide sheets – an appropriate method by which to produce insights into the standard-setting process and to consider how those involved view the process. Interviews, alongside observations and document analysis, were the research methods used in the production of the case-study, given the focus upon process. When considering the main emphasis of a process-oriented account, Becker (1992: 208-209) suggests: “A process or narrative analysis has a story to tell...The process is taken to be important to the result, perhaps even constitutive of it.” The production of the case-study is thus the analysis of the process which has produced the case-study, along with consideration of how the researcher has actively worked to produce that case-study.

As discussed above, the study became increasingly concerned with the process of standard-setting. Throughout the study, interviews were conducted, observations made and noted and documents consulted and analysed. At particular stages in the development of the case-study the interviews took different forms. In the scoping stages, interviews with civil servants in the UK FSA were exploratory and partly concerned with fact-finding. They were structured in the sense that I asked questions about specific aspects of the Codex, but were fluid as I had little concern to stick rigidly to speculative questions. Following Bryman (2004), the level of structure in interviews is an important consideration and is closely linked to the nature of the inquiry being conducted. In trying to access the views of participants, it is appropriate to follow an interview guide which is not too rigid. As Arskey and Knight (1999) suggest, interviews allow for the opportunity to not only explore perspectives on an issue, but also to improvise questions as they emerge. Indeed, the emergent aspect of interviews may be their most important contribution to study. Interviews were used in the early stages of the study to refine the case. With the development of the case-study, interview guides took on a more rigid form. Questions posed to scientists also differed from those posed to government officials. For example, a typical interview guide for a government official would include questions about the institutional responses to the debate over dietary fibre and the importance of Codex standards to the work of their department or agency. In contrast, questions to scientists focused upon the scientific debate over

dietary fibre. However, there was considerable cross-over in the intention of the interviews. A standard approach in all interview guides was to initially ask about the professional background of the interviewee. This served two purposes; it allowed the interviewee to relax into the interview by talking about themselves and also produced interesting information on how the interviewee had come to be concerned with the topic in question. The second aspect of this approach provided an opportunity for further questions.

In developing the case-study, interviews were conducted in a variety of contexts. Some, as mentioned, were conducted in and around Codex meetings (as discussed in Chapter Four). Many were conducted over the telephone. Telephone interviews were the most cost effective method of interviewing research participants situated across many countries. While conducting interviews at Codex meetings was convenient (all the interviewees were present in one place and I could speak with them face to face), Codex meetings were also a difficult place to undertake such activities given that delegates are very busy undertaking work. I found that in some cases, a more useful approach was to make contact with a delegate at a meeting, leave a research summary and business card with them, and follow-up with an email or telephone call to arrange an interview. In this way an interview had much more chance of success. Telephone interviews are convenient for participants with demanding roles as they can be scheduled around the working day and require minimal effort. Most interviews conducted were digitally recorded, except when a participant expressed a desire not to be recorded. In these cases notes were taken. Equipment was used to make possible the digital recoding of telephone interviews. In total thirty-two interviews were conducted: thirteen with government officials, nine with dietary fibre scientists, six with industry group representatives, two with academics, one with a Codex risk assessor and one with a consumer group representative. Allied to this were numerous discussions and emails with research participants. In order to respect confidentiality and to adhere to research ethics, interviewees were given the opportunity to complete a consent form (see Appendix I). The consent form set-out the terms upon which any interview would take place and the permissions necessary for the use of the material produced. A list of interviews is provided in Appendix II, though the identity of participants has been anonymised.

Negotiating and conducting interviews with government delegates, industry group representatives and senior scientists is a form of elite interviewing – a term applied to interviews conducted with individuals occupying high-level political positions, leaders in particular fields and senior roles in organisations. In discussing the latter, Delaney (2007) applies the term ‘organisational elite’. He suggests that, despite the connotations of the term, organisational elites are not, as a general rule, difficult to access, although this is dependent upon the issue in question. Conducting an interview on a controversial issue can have two effects upon organisational elites. On the one hand, conducting research on a controversial issue ensures that prospective interview participants are interested in engaging in order to ensure their views are represented. Alternatively, the controversial nature of the issue may dissuade potential interviewees from participating. In this study, both these effects were in evidence, though the majority of government delegates, industry representatives and consumer groups were willing to be interviewed. Senior scientists were even more willing to engage in the research and actively commented on subsequent writing. The causes of a non-response are inherently difficult to ascertain. For instance, it proved difficult to arrange interviews with Codex secretariat and Chairpersons, but this could be explained by pressing workloads.

The interviews comprised questions and discussions relating to a specific process of standard-setting – agreeing the definition of dietary fibre – and so concentrated on the substantive issues. The intention was to gain an understanding of how government delegates conceptualised the controversy and to reveal their points of reference in the debate. The agreement of a definition for dietary fibre had not been settled at the time most interviews were conducted and so they provided an insight into the on-going process. The focus in the study upon the standard-setting process meant that inference about the responses of interviewees emerged through a dialogue over the history of the standard, including personal history. In this way knowledge about the background and expertise of delegates could be subtly produced.

Transcriptions of interviews and discussions and relevant documents were ordered and analysed using Nvivo software. Nvivo assists in the arrangement of qualitative data and allows for the coding and categorisation of text. According to Bryman (2004), qualitative data analysis conducted using computer software (such as Nvivo) requires decision-making over the coding of material and interpretation. In this respect, he



suggests that all analysis, including quantitative analysis, requires creativity on the part of the researcher. Concern has been raised over the possibility that the use of software packages imposes rigidity upon data interpretation (Coffey *et al*, 1996). However, in this study Nvivo was used as means of organising and arranging data. While some coding was conducted in order to generate emerging themes, the overall sample size was relatively small and so no categories were established with the explicit purpose of interrogating the entire sample. Such an approach was entirely justified given the limited number of participants relevant to the case-study. The aim was not to account for general patterns across a large sample, but instead to address how participants understood and were active in the process of standard-setting. The use of a software package provided a useful means of scanning across transcripts and generating associated links to other transcripts, though this did not replace the need for frequent references to the original digital recordings and/or notes. Within these activities, categories were produced to assist analysis, not as the units of analysis. As a result, Nvivo was used as a tool to aid the analysis process, rather than the basis upon which all analysis would follow.

Respondent validation – the provision of data and writing to research participants – proved an interesting technique and was used in three main ways. Firstly, permission was sought to use data in thesis chapters and in published work. Many interviewees expressed a desire to change the presentation of the data for reasons of sensitivity. Obviously these reasons cannot be explained here. Secondly, Chapter Five – which deals with the history of dietary fibre science and technology – was sent to the dietary fibre scientists who were most closely involved as interviewees and informants. I was interested not only in ensuring they had a chance to read how the data had been used, but also to contribute to a discussion of the arguments presented in the chapter. In this sense, Chapter Five itself became not only an analysis of the history of defining dietary fibre, but also a ‘live’ text to be debated over. The participants engaged with this exercise and provided insightful reasoning as to why certain changes could be considered. Thirdly, the analysis of the Nutrition Committee presented in Chapter Four was sent to a number of government regulators, for similar reasons as above. However, engagement with the technique was more variable.

Although interviews were important research methods used in this study, observation and document analysis were also crucial to the account presented. Observational work was conducted at the Codex Commission meeting, the Codex Nutrition Committee and the UK Scientific Advisory Committee on Nutrition (SACN). In addition, interviews were conducted in other settings which allowed for further observations. For example, an interview was conducted at a food analysis laboratory which allowed for the active discussion of the methods used and a demonstration of how the method is used in application. Observation in the sense used in this study conforms closely to what Gold (1958) terms ‘observer-as-participant’, in the sense that interactions with research participants were not conducted in a continuous manner. However, contact was maintained with a well developed group of participants, some of whom were interviewed twice, while others provided additional comments and documentation. In choosing a case-study focused upon the standard process for one Codex standard, inevitably a distinct group forms of those who appear to be most closely involved in the issue. In particular, a core-set of scientists (see Collins, 1981 in Chapter Two), closely involved in the definition of dietary fibre, contributed interviews and comments.

In considering observational work conducted with low-levels of participation in the process being observed, Moug (2004) has used the term non-participative observation. He considers this a valuable mode of inquiry, particularly when access is difficult, and notes that events which occur infrequently can pose particular problems for research. In some circumstances, the ability to choose whether to be a participant in a process might not be available. It may also compromise the position of the researcher within the field; though this is not to say the researcher can be removed from the study. The approach to research taken here cannot be described as removed from the object under inquiry; a major aim of this Chapter is to reveal how a case-study is put together, rather than being fully formed before the researcher enters the field. However, it is still possible that gaining access to a process through affiliations to a particular organisation or government might not necessarily lead to a convincing account. The study presented here involved close engagement with participants in the Codex standard-setting process, but did not constitute participant observation as conventionally understood. Instead, it involved interactions in and around Codex meetings – followed up with emails and interviews – which were more than passive observation but did not directly impact upon the live process as it unfolded.

The Codex standard-setting process is document intensive. Documents arise from previous reports, comments submitted by member governments and observer groups, outcomes from other meetings and a variety of other sources. Many documents are available online through the Codex website, once they have been finalised and published. Others, however, are made available during meetings. Often they are published in the form of conference room documents and provide an opportunity for members to submit comments and propose amendments during the meeting. Active observation of meetings involves collecting these documents and affords an opportunity to have informal conversations with delegates. However, the position of the researcher is again an issue under such circumstances. In theory, being granted public observer status at a Codex meeting means that access is restricted to the public gallery and no other area. In practice, this divide is not rigorously maintained, so long as access to the meeting room floor (where the documents are located) is not abused.

### 3.4 Introducing the Empirical Analysis

The aim of this Chapter has been to provide an account of the research design and methods of investigation. In this discussion the emphasis has been upon the means by which the case-study was produced. Section 3.2 provided an explanation of the scoping activities conducted to refine the case-study and elucidated the key operational aspects of the Codex as an institution. Understanding the operation of the Codex was a key step in identifying a case-study. Section 3.3 considered the methodological approach of the study. The rationale for the utilisation of particular research methods was set-out and an account given of how these methods were applied in practice.

The following three chapters – Chapters Four, Five and Six – constitute the principal empirical analysis of the thesis. Chapter Four is concerned with the treatment of dietary fibre as a regulatory dilemma with the Codex. The emphasis is upon understanding how the standard-setting process unfolds when dealing with a contentious issue. Chapter Five considers the history of the controversy over dietary fibre from the perspective of science and technology. The chapter identifies how disagreement between scientists became entangled within the regulatory dilemma discussed in

Chapter Four. The final empirical chapter – Chapter Six – concentrates upon the production of knowledge claims over dietary fibre within four domains: the European Commission, UK, US and the FAO/WHO. It also addresses how disputes over the methods of analysis and measurement are symptomatic of the trans-scientific nature of the contention over defining dietary fibre.

## Chapter Four – Dietary Fibre as Regulatory Dilemma

### 4.1 Introduction

In the international regulation of the agri-food system, science plays a prominent role. Within the Codex system, science is regarded as the basis upon which international food standards are produced. However, as suggested in Chapter Two, when science is involved in policy-making it is often unclear where science ends and policy-making begins. Science and policy-making become entangled. If scientific activity is on-going and scientific evidence is not conclusive, this relationship becomes further complicated. In such a scenario, the construction of a scientific fact (Fleck, 1935/1979) becomes an important component of policy-making. Following Jasanoff (2004; 2005), science and policy are co-produced, with the regulatory scientific activity and policy-making mutually constitutive. In this sense, the suggestion that scientific facts are constructed does not imply a belief that science has no basis in reality. Instead it acknowledges that scientific facts are produced by a process, and that this process is worthy of attention due to the multiple interpretations involved.

The activity of constructing scientific facts within a policy-making environment is subjected to close analysis in this Chapter. The Chapter is concerned with the process of agreeing an international definition for dietary fibre in the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (hereafter referred to as the Nutrition Committee in this chapter), as part of a Codex standard ‘Guidelines for Use of Nutrition and Health Claims’ (hereafter the Claims Standard). As will be discussed, this process turned upon the interpretation and use of diverse and inconclusive sources of scientific advice. Contention and contestation characterised the process. However, as noted in Chapter Two, Kuhn (1962/1996) suggests that often competition between competing scientific paradigms cannot be resolved by scientific proofs. Instead, controversy is resolved by other means. Disagreement over the definition of dietary fibre is the focus of this Chapter. The eventual resolution of the contention is taken-up in Chapter Six, which deals with the broader negotiation of the definition within particular political arenas. The focus in this Chapter is upon the processes leading up to the eventual agreement.

From 10-16 November 2007 I attended the 29th Session of the Nutrition Committee, in Bad Neuenahr-Ahrweiler, Germany. As detailed in Chapter Three, the Nutrition Committee is a subsidiary Codex committee which deals with standards pertaining to the nutritional and dietary aspects of internationally traded food. I spent much of Saturday 10th in a pre-meeting working group which discussed a Codex standard for gluten-free foods. On Sunday morning I attended a workshop hosted by the International Life Science Institute (ILSI). Both these events were particularly instructive as to how Codex standards are put together. The ILSI event, titled 'Pre-Codex Meeting on Dietary Fibre', also alerted me to the contention which exists over the definition of dietary fibre. As the Nutrition Committee meeting proceeded (officially) from Monday 12<sup>th</sup> onwards, I began to realise that the relatively low-key controversy over dietary fibre (though a persistent one in the Nutrition Committee) involved a complex interaction of science and policy-making. Essentially, the issue, which is still under discussion, deals with the scope of substances that can be considered as dietary fibre and the methods for analysing these substances. This has implications for the substances included in food products, the emergence of fibre fortification products, labelling information (including dietary recommendations) and the nutritional claims made by food manufacturers.

Why is defining dietary fibre so contentious? As commonly understood, dietary fibre is regarded as a beneficial component of food. To say that a food product is a 'source of fibre', or better still 'high in fibre', is to imply it is healthy, wholesome and natural. Dietary fibre has come to be associated with certain food groups, primarily fresh fruit, vegetables and wholegrain foods. The pervasiveness of this common understanding of dietary fibre has provoked contention over the appropriate means of defining and measuring dietary fibre. New perspectives and developments in food science and technology have led scientists, regulators and food company representatives to suggest varying definitions for dietary fibre. Innovations in food science and technology have produced new ways of thinking about dietary fibre and utilising compounds that might qualify as dietary fibre, such as oligosaccharides.<sup>22</sup> Broader definitions of dietary fibre, beyond materials found naturally in plant cell walls, encompass processed and synthetic food substances. Food companies have begun to invest heavily in the development of

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<sup>22</sup> As found in food products marketed as prebiotics.

fibre fortification technologies. Indeed, it has been suggested that there has been an “explosion of gut health technology” (Arens, 2008: 10). The use of these novel technologies turns on the physiological effects that fibre fortification might have in the human gut, such as lower blood cholesterol and laxative effects. Investment in these innovations is not undertaken lightly and food companies are actively pursuing mechanisms by which to market and differentiate these products. One important mechanism is to make nutritional and/or health claims for food products.

Making claims for food products is a major pre-occupation for food companies given the highly competitive market in which they operate. Food companies are paying ever greater attention to the production of food products with health claims, in a search for market differentiation and added-value. As a result, the concepts and components used to describe and identify food products – through food labels – are under constant scrutiny (Bostrom and Klintman, 2008). Contention over the definition of dietary fibre is occurring in a context of heightened activity in this broad area of food manufacture, often termed ‘functional foods’ or ‘nutraceuticals’. Both these terms refer to the production of food products which are sold by the producers on the basis of health and nutrition claims, such as ‘lowers cholesterol’ or ‘promotes healthy teeth and bones’. According to a marketing report by Leatherhead Foods International, the global market for those foods making a specific health claim stood at around \$16bn in 2005, while the global market for food products which encompass health claims without explicitly stating them stood at \$36.2bn (Leatherhead Foods International, 2006). The importance of health claims for food products has also been noted by Lang and Heasman (2004: 127), who suggest that: “Food companies have an increasing interest in health which they apply to marketing and product development, despite the decades spent resisting nutrition policy analysis.” The significance food companies attach to the functional, nutritional properties of food products has led to a growing range of health-oriented food products. This has been partly driven by investment in food science and technology. In Europe, research and development activity has been focused upon the exploration of particular food ingredient categories, such as prebiotics, probiotics, vitamins and minerals, fish oils and plant sterols (Hilliam, 1998). Activity has also focused upon dietary fibre, in particular health claims for soluble fibre as cholesterol-lowering. Claims for the health benefits of dietary fibre have featured on breakfast cereals and some breads, but relatively few other food products have produced fibre-

related claims as yet.<sup>23</sup> The struggle over definitions of food attributes and the methods used to identify these attributes possess a significant challenge to regulators.

The following section focuses upon how dietary fibre has come to be defined in the Codex system. By way of introduction, the main decision-making events relevant to the eventual adoption of a Codex definition of dietary fibre are given in the following:

2009	Adoption of Codex definition of dietary fibre in the Codex Commission without agreed methods of analysis.
2008	Agreement of dietary fibre definition in Codex Nutrition Committee. No agreement on methods of analysis.
2007	FAO/WHO present main findings of the published Scientific Update to the Codex Nutrition Committee. Consensus is not forthcoming.
2006	FAO/WHO indicate findings of Scientific Update to the Codex Nutrition Committee. Scientific Update to be published in 2007.
2002	US Institute of Medicine of the National Academies report on dietary reference intake, including dietary fibre.
1998	Informal Codex working group on dietary fibre established by the Codex Nutrition Committee. The working group suggest expert consultations may be necessary.
1992	Work on nutrient descriptors, including dietary fibre, initiated by the Codex Nutrition Committee in 1992 as requested by the Codex Food Labelling Committee

*Figure 4.1: Time line of main decision-making events*

The development of a definition and its adoption in 2009 has occurred in a context of pressure by food companies to utilise the dietary fibre concept as a means of marketing food products. The origins and history of the concept of dietary fibre, which first emerged in the early 1970s through the work of Denis Burkitt and Hugh Trowell, will be dealt with in Chapter Five. In this chapter the focus is upon the regulatory processes which have lead to controversy over defining dietary fibre and agreeing on a method of analysis.

<sup>23</sup> Hilliam (1998) notes, a major market for fibre-containing drinks exists in Japan, where the concept of functional foods emerged in the mid-1980s.



## 4.2 The Scope and Content of a Definition for Dietary Fibre

In 2007 the Nutrition Committee defined dietary fibre, in draft form, as follows:

Dietary fibre means carbohydrate polymers with a degree of polymerisation (DP) not lower than 3, which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture.

Dietary fibre consists of one or more of: edible carbohydrate polymers naturally occurring in the food as consumed; carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means; synthetic carbohydrate polymers.

(Codex, 2007a)

This definition requires some explanation. It has a particular history and it uses technical language. Dealing with the technical terms, carbohydrate polymers are those carbohydrates composed of three or more monosaccharide units linked together. According to Asp and Bender (2005), those carbohydrate polymers with between three and nine monosaccharide units are termed oligosaccharides and those with more than nine units are termed polysaccharides. As the second sentence of the draft Codex definition suggests, a focus upon carbohydrate polymers with three or more monosaccharide units excludes mono- and disaccharides from being considered as dietary fibre. So, the first part of this draft definition states that dietary fibre is not restricted to polysaccharides. This is significant. As will be discussed in more detail, dietary fibre had been associated with non-starch polysaccharides only. Non-starch polysaccharides are, simply put, those polysaccharides found in plant cell walls which are not starches. The draft Codex definition extends the boundaries of what can be considered as dietary fibre beyond non-starch polysaccharides.

The second element of this draft definition clarifies what can be considered as dietary fibre from the perspective of the manufacturing process. The definition states that dietary fibre can comprise carbohydrate polymers extracted from food raw materials (plants) using a number of methods, including physical, chemical and enzymatic extraction. The suggestion here is that ingredients in food products which are extracted

from plants can be considered as dietary fibre. Extracts may then be used in the manufacture of food products and can contribute to the amount of dietary fibre in that product. It is therefore possible, by this definition of dietary fibre, to fortify food products with dietary fibre by using food substances high in dietary fibre (by the measurement allowed under the definition). Dietary fibre can comprise synthetic carbohydrate polymers, such as oligofructose (produced by enzymatic methods) and resistant maltodextrin (produced by chemical methods).

The draft definition has a number of other features (such as properties of dietary fibre, recommendations for use and methods of analysis) which will be discussed later. In order to be able to contextualise these features, and to unpack the technical concepts used, it is necessary to examine the origins and development of the definition for dietary fibre within the Codex system. The elaboration of the definition can be traced to work undertaken on the Codex Claims Standard (Codex, 1997). The early draft of the Claims Standard was proposed by Canada at the 1991 meeting of the Codex Committee on Food Labelling (Codex, 1991a). The Codex Committee on Food Labelling (hereafter the Food Labelling Committee) sought advice from the Nutrition Committee on a specific part of the Codex Claims standard; nutrient descriptors. As a result, the Nutrition Committee became active in developing this specific aspect of the Codex Claims standard. Nutrient descriptors are used on food packaging to indicate levels of particular nutrients present in the food, such as energy, fat, sugars, vitamins and minerals etc. Dietary fibre is also included within these descriptors. What follows is a chronological summary of the key points of discussion which took place within the Codex system on the issue of defining fibre from 1992 to 2000. It should be noted that the term 'fibre' was used in these discussions until 2000 when it was replaced by the term 'dietary fibre'.

In 1992 the 18<sup>th</sup> Session of the Nutrition Committee considered how to establish nutrient descriptors, as requested by the Food Labelling Committee and approved by the Codex Commission (Codex, 1991b). According to the report of this meeting, some delegations expressed concern at the inclusion of health claims in the Codex Claims standard, though they were reminded by the Chair – Arpad Somogyi of Germany – that they were not mandated to discuss the scope of the guidelines (Codex, 1993). The scope of the guidelines was set by the Food Labelling Committee (Codex, 1991). With

regards to fibre, nothing was agreed at the 1992 meeting and the values for ‘source of’ fibre and ‘high in’ fibre were placed in square brackets for further discussion. The nutrient descriptors, which the Nutrition Committee was mandated to set, were to be entered into a ‘Table of Conditions’ (hereafter the Table). The lack of consensus over some of the nutrient descriptors to be included, including fibre, meant that the Table could not be agreed in its entirety. In order to proceed with the submission of nutrient descriptors to the Table, the Table was split into two parts. Energy, fat, saturated fat, cholesterol, sodium and sugar were placed in Part A of the Table, while fibre, protein and vitamins and minerals were placed in Part B. By splitting the Table, the Nutrition Committee could attempt to agree on some nutrient descriptors in the near future and report these to the Food Labelling Committee. This meant that more contentious nutrients could be dealt with at a later date.

The next session of the Nutrition Committee was held in 1995. Here it was proposed that ‘source of fibre’ could be used on food products containing a minimum of 3g / 100g (or 1.5g / 100kcal) and ‘high in fibre’ to those with a minimum of 6g / 100g (or 3g / 100kcal) (Codex, 1996). The US expressed disagreement with these values. It was also noted that establishing the definition of fibre and the appropriate methods of analysis was problematic and would require further work in order to give values for nutrient descriptors. While the Nutrition Committee considered the specific details of the nutrient descriptors for the Codex Claims standard, the Food Labelling Committee had already continued to advance the remainder of the text (Codex, 1995). In 1996, the Codex Claims standard (minus the Table) was advanced to Codex Step Eight by the Food Labelling Committee in order to be considered for adoption by the Codex Alimentarius Commission (Codex, 1997a). The advancement of the Codex Claims standard by the Food Labelling Committee gave impetus to the next meeting of the Nutrition Committee, in 1996. Here it was agreed that Part A of the Table could advance with the Codex Claims standard to the Codex Alimentarius Commission for adoption (Codex, 1997b) . However, Part B of the Table was returned to Step Six for further discussion. Again it was noted that establishing a definition of fibre and agreeing suitable methods of analysis posed significant difficulties, though the report of the meeting does not say why this was thought to be the case. The Codex Claims standard, including Part A of the Table, was adopted at the 22<sup>nd</sup> Session of the Codex Alimentarius Commission in 1997 (Codex, 1997c). In adopting the Codex Claims

standard it was noted by Spain that further work was required on fibre and this required scientific evaluation.

The Nutrition Committee met again in 1998. By the end of this meeting Part B of the Table had been recommended for adoption by the Codex Alimentarius Commission (Codex, 1999b). However this only included protein and vitamins and minerals. Nothing had been agreed for fibre. In progress the work on fibre, four issues were identified for further discussion: the definition of fibre, the method of analysis for measuring fibre, the development of appropriate Nutrient Reference Values and the discrepancies in the results obtained when declaration was made per 100 g or per 100 kcal. With regard to the last issue of nutrient measurements, Brazil proposed using figures per 100ml to incorporate fibre present in liquids, especially fruit juices. Whilst some progress was made on agreeing units of measurement for fibre content, little attempt was made to advance a definition or method of analysis. Instead an informal working group was established, chaired by the UK. Australia, Brazil, Canada, Denmark, France, Germany, Hungary, Korea, New Zealand, South Africa and the US were all named as participants in this working group. A consultation paper was issued on 9<sup>th</sup> October 1998 to begin the work of this group.

As a result of the 1998 meeting of the Nutrition Committee, the Table was split again. The provisions on protein and vitamins and minerals were advanced for adoption by the 23<sup>rd</sup> Session of the Codex Commission, though they failed to be adopted (Codex, 1999a). The provision on fibre was held at Step 6 for further comments. At this stage the Table as relating to fibre looked as follows:

**DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS (Part B)**  
**(DRAFT GUIDELINES FOR USE OF NUTRITION CLAIMS)**  
**(At Step 6 of the Procedure)**

COMPONENT	CLAIM	CONDITIONS
B.		NOT LESS THAN
Fibre	Source	3 g per 100 g or 1.5 g per 100 kcal or per serving <sup>21</sup>
	High	6 g per 100 g or 3 g per 100 kcal or per serving

*Figure 4.2: Draft Table of Conditions*

Following the meeting in 1998, the working group chaired by the UK began to produce responses (Codex, 2000b). On the issue of defining fibre, attempts to reach a consensus by agreeing on the health benefits or physiological effects of fibre were not successful as some countries rejected this approach. On the subject of methods of analysis, it was noted that methods approved by the Association of Analytical Communities (AOAC) were widely used for nutrition labelling<sup>24</sup>. Given the lack of agreement, the report of the working group suggested that one means of progressing debate would be to have an expert consultation.

In June 2000 the Nutrition Committee reconvened for its 22<sup>nd</sup> Session (Codex, 2000c). Nine countries submitted comments ahead of this meeting in relation to dietary fibre (Codex, 2000a). Both Spain and the UK suggested that it would only be possible to agree on the values to be included in the Table once a definition for fibre had been settled and the methods of analysis established. The most substantive set of comments came from Australia and suggested some modified values for fibre. In discussions at the meeting it was proposed that the definition for dietary fibre be linked to those methods approved by the AOAC and which were recognised by the Codex Committee

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<sup>24</sup> The Association of Analytical Communities (AOAC) was founded in 1884 as the Association of Official Agricultural Chemists under the USDA to develop uniform methods for the analysis of fertilisers. By 1965 the AOAC was known as the Association of Official Analytical Chemists and sought further independence from the US Food and Drug Administration. In 1987 full voting membership was established for non-government scientists. The name Association of Analytical Communities was adopted in 1991, eliminating reference to particular disciplines or to the previous focus upon government analysts (AOAC, 2010).

on Methods and Sampling (hereafter the Methods Committee), though some countries did not think this resolved problems of definition. The FAO drew attention to the consideration of fibre in the FAO/WHO Expert Consultation and Carbohydrates in Human Nutrition (FAO, 1998b). Both the US and Sweden stated that they were in the process of producing national reports which would deal with fibre. Sweden also expressed agreement with the comments of Japan (Codex, 2000a) with regard to the use of the term ‘dietary fibre’ rather than ‘fibre’, in accordance with international practice. From this point onwards the term dietary fibre was applied. However, nothing else on dietary fibre was agreed at this session of the Nutrition Committee. The Table (dietary fibre) was returned to Step 6 for further discussion.

The 23<sup>rd</sup> session of the Nutrition Committee met in 2001 (Codex, 2002). Here the US and Sweden both reiterated they would soon be able to publish reports covering the definition of dietary fibre. The issue of whether dietary fibre should cover plant and animal material, or only plant material, was raised. In relation to this proposal, it was noted that the Guidelines on Nutrition Labelling (Codex, 1985)<sup>25</sup> includes a definition of dietary fibre, as follows:

Dietary fibre means edible plant and animal material not hydrolysed by the endogenous enzymes of the human digestive tract as determined by the agreed upon method.

No agreement was reached on dietary fibre and the Table (dietary fibre) was held at Step Seven. It was noted that new scientific evidence would be forthcoming for the next session of the Nutrition Committee.

At this point it is helpful to review how the definition of dietary fibre had become an issue within the Codex system. Work on nutrient descriptors was initiated by the Nutrition Committee in 1992 as requested by the Food Labelling Committee. The Nutrition Committee spent time in each of the next six sessions (in 1992, 1995, 1996, 1998, 2000 and 2001) attempting to agree on a table which would include values for

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<sup>25</sup> The on-going revision of this Codex standard is related to the Codex Claims standard, but a thorough account of these discussions is not possible here. As an indication, at the 36<sup>th</sup> Session of the Codex Food Labelling Committee held in 2008, some member governments suggested that dietary fibre be included in the list of nutrients that are always declared on food labels.

nutrient and health claims. Some of this table (Part A) was adopted by the Codex Commission in 1997 and so the Codex Claims standard had values for several nutrient descriptors. For instance, it was agreed that for a product to claim to be 'low in fat' it could contain no more than 3g per 100g for solids and 1.5g per 100ml for liquids. This was premised upon an agreed definition for fat. However, Part B of the table, which included values for dietary fibre, remained open for discussion. These values remained in square brackets, signifying they had not been agreed by the Nutrition Committee. Discussion over dietary fibre had seemingly reached an impasse in 2000 with no agreement on the values for 'source of fibre' and 'high in fibre' possible until a definition had been agreed and methods of analysis established. With this in mind, at the 2001 meeting of the Nutrition Committee member governments began to state that they would produce evidence in relation to the definition of dietary fibre and the methods of analysis. The US and Sweden suggested they would soon be in a position to produce national reports dealing with these questions (a Nordic report in the case of Sweden). At this point the discussion of dietary fibre in the Codex system began to respond directly to national forms of scientific evidence. Prior to this, discussion had been relatively limited. Indeed, the working group chaired by the UK in 1998 suggested that expert consultations were necessary in order to progress debate.

As detailed above, the discussion of an appropriate definition for dietary fibre took a slow pace in the Codex system from 1992 until 2001. When discussion moved beyond the values to be placed in the Table and considered the definition of dietary fibre and methods of analysis, little progress was made. One suggestion by the working group formed in 1998 was that an expert consultation may help the process (Codex, 2000b). However, the FAO/WHO had held a Joint Expert Consultation on Carbohydrates in Human Nutrition in April 1997 which covered the definition of dietary fibre and methods of analysis (FAO, 1998b). In considering dietary fibre, the expert group recommended:

That the use of the term dietary fibre should always be qualified by a statement itemizing those carbohydrates and other substances intended for inclusion. Dietary fibre is a nutritional concept, not an exact description of a component of the diet.

Earlier in the report, the group had suggested that:

While there is general agreement that the non-starch polysaccharides are the principal part of dietary fibre there is currently no consensus as to whether other components should be included in this term. It has been suggested that the use of the term dietary fibre be gradually phased out. Its widespread use and popularity with the consumer has made this difficult in practice and the term has been useful in nutrition education and product development.

And so the FAO/WHO had not offered a strict definition of dietary fibre as a result of the expert consultation. Instead, dietary fibre was regarded as a term with popular public significance whilst simultaneously a term that should be qualified when used. Also, it was stated that no agreement existed on which components (in addition to non-starch polysaccharides) ought to be included in the definition of dietary fibre. Despite the work of the FAO/WHO expert group, their rather broad, and even contradictory recommendations, did not settle the discussion on dietary fibre in the Codex. Instead, some national governments undertook their own reviews.

The US and Canada were the first to publish relevant evidence with the Institute of Medicine of the National Academies<sup>26</sup> (IoM) report 'Dietary Reference Intakes for Energy, Carbohydrate, Fibre, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids' (IoM, 2002). The report was produced by the Food and Nutrition Board of the IoM and ran in excess of 1000 pages. It dealt with a variety of topics and included a chapter on 'Dietary, Functional and Total Fibre'. A 'Panel on the Definition of Dietary Fibre' was assembled to produce this chapter, taking into account public comments. Three definitions of fibre were proposed: dietary fibre, functional fibre and total fibre. According to these definitions, dietary fibre consists of non-digestible carbohydrates and lignin that are intrinsic and intact in plants, whilst functional fibre consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans. Total fibre is the sum of dietary and functional fibre. One justification for creating a category of functional fibre is to allow for the following:

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<sup>26</sup> The Institute of Medicine is a component of the National Academy of Sciences (NAS).



In the relatively near future, plant and animal synthetic enzymes may be produced as recombinant proteins, which in turn may be used in the manufacture of fiber-like materials. The definition will allow for the inclusion of these materials and will provide a viable avenue to synthesize specific oligosaccharides and polysaccharides that are part of plant and animal tissues.

(IoM, 2002)

The US presented the findings of the NAS report to the 24<sup>th</sup> Session of the Nutrition Committee in 2002 (Codex, 2003b). At the same meeting it was agreed that France would lead the production of a discussion paper on dietary fibre, to be presented at the next session of the Nutrition Committee. The delegation of France had also stated that it was undertaking work on a national basis on the question of defining dietary fibre, through the Agence Francaise de la Securite Sanitaire des Aliments (AFSSA), while the delegation of Sweden gave an update on the development of reference intake work on fibre. National governments were therefore actively engaging in the production of scientific evidence and policy positions with regard to dietary fibre, while also participating in discussions in the Codex system. Also, the Codex observer groups Confederation of Food and Drink Industries of the EEC (CIAA), International Dairy Federation (IDF) and International Special Dietary Foods Industries (ISDI) and International Baby Food Action Network (IBFAN) became active participants in the production of the discussion paper. In short, by 2002 there was a significant increase in regulatory science being conducted by Codex members on the issue of dietary fibre.

The Nutrition Committee met again every year from 2003 to 2006. At each meeting the definition of dietary fibre was discussed, with little consensus. In 2005, the decision was taken – in view of support by several delegations – to include all non-starch polysaccharides with a degree of polymerisation not lower than three. This represented an important step in the development of the draft definition in Codex and extended the parameters of what could be considered as dietary fibre. At the same meeting the FAO/WHO representative suggested that work was being undertaken on the physiology of carbohydrates and that this would include recommendations on the definition of dietary fibre. At the 2006 meeting the FAO/WHO presented a definition of dietary fibre which ran counter to that developed in the Nutrition Committee.

### 4.3 In and Around the Nutrition Committee

Thus far, this Chapter has detailed how the contention over the definition of dietary fibre and method of analysis developed within the Codex system from 1992 until 2002. The previous section began with the current draft definition of dietary fibre which was discussed at the 29<sup>th</sup> Session of the Nutrition Committee held in November 2007. In this section an account of the 2007 Nutrition Committee is provided, focused in particular upon the discussions over the definition of dietary fibre. The aim is demonstrate how standard-setting takes place in and around a technical Codex committee. There is a tension between the accounts to be found in the formal summaries of Codex reports and the formal and informal activities which make up standard-setting in this case.<sup>27</sup>

The following is an account of the 2007 meeting of the Nutrition Committee. Prior to observing the Nutrition Committee meeting I attended a workshop held by the International Life Sciences Institute (ILSI), which highlighted the contention over dietary fibre through presentations and discussions. According to the ILSI website:

Founded in 1978, the International Life Sciences Institute (ILSI) is a non-profit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, and industry.

The major sponsors of ILSI are food and pharmaceutical companies, including Nestle, Masterfoods, Kraft Foods, Kellogg, GlaxoSmithKline, Monsanto, Dow, Unilever and Heinz. The organisation is headquartered in Washington, D.C. and has regional branches such as ILSI Europe, ILSI Southeast Asia and ILSI India. I attended this ILSI meeting as a member of the public, having already registered to attend the Nutrition Committee as a public observer. In particular I wanted to interview Loek Pijls, whom I had been introduced to via email by a nutrition scientist at Newcastle University. Pijls

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<sup>27</sup> A member government representative questioned whether the term 'tension' was a fair description of the relationship between the discussions which happen in meetings and the eventual report of the meeting, given that member states have the chance to amend the draft final report on the last day of Codex meetings. I have retained the term tension and in doing so draw attention to these interesting exchanges.

was then Senior Scientist at ILSI Europe. When I first contacted him about holding an interview he drew my attention to the ILSI workshop, which was being held as a pre-Codex event. This conferred a sense of endorsement by the FAO/WHO upon the event. I had presumed that access to such side-events would be restricted, but I was invited by Pijls to attend.

When I arrived for the ILSI meeting Pijls was outside organising name badges and information packs. I introduced myself and he said we could meet afterwards as arranged via email. I had not been included on the participants list so I filled out a name badge and found a seat. A member of a government delegation – whom I had met the previous day – sat next to me. The government delegate began to explain to me what the meeting was about, how there was a method for detecting dietary fibre – the Englyst Method – which did not capture synthetic fibre. The delegate suggested that dietary fibre reflects a diet i.e. a diet high in wholegrains, fruits and vegetables and also mentioned the Scientific Update on Carbohydrates in Human Nutrition undertaken by the FAO and WHO.

The meeting began with an introduction from Eric Hentges, Executive Director of ILSI North America and Head of the ILSI delegation to the Nutrition Committee. He has previously served as Executive Director of the USDA's Centre for Nutrition Policy and Promotion, as well as serving on the US National Pork Board, the National Pork Producers Council and the National Live Stock and Meat Board. Eric introduced ILSI as an organisation, mentioning that it enjoys affiliation with the WHO. He said the purpose of the meeting was to provide scientific advice on dietary fibre and he introduced the three talks to be given. The first, titled 'Defining dietary fibre from a historical perspective', was by Julie Miller Jones, Professor of Nutrition and Food at College of St. Catherine, Minneapolis. She is a former president of the American Association of Cereal Chemists International (AACCI). The scope of her talk dealt with the development of the dietary fibre hypothesis and methods of analysis. The second talk was by Barry McCleary, CEO and founder of Megazyme International Ireland Ltd, and was titled 'Analytical methods for measuring dietary fibre in food matrices'. The final talk, on 'Current understanding of the physiological effect of various fibres' was by Marcel Roberfroid, Professor Emeritus of Biochemistry and Toxicology at the University of Louvain and former President of ILSI Europe. Taken

together these talks, on definition, methods and physiological effects, set-out the ILSI position on dietary fibre. Indeed, in 2006 ILSI published a concise monograph titled 'Dietary fibre: definition, analysis, physiology and health' (Gray, 2006). Importantly the audience for these talks was mainly composed of delegates from Codex member governments. Speaking afterwards about the ILSI workshop, Pijls suggested that:

This morning what we typically do is, I mean ILSI is involved, here is all the people, all the delegates are here. We have work that is on the committee agenda, we so simply take the opportunity to bring people's attention to scientific work we have done, so they can become more aware of the scientific basis that is out there for the topics they want to talk about this week. We hope by having this event, it will help people when they are talking about, for example fibre, hopefully tomorrow, in the meeting, and so, of course we think it is good for ILSI but also it is visibility to show our work because dissemination is very important for us, we always want to disseminate our work as much as we can, because the more disseminated it is the more impact it will have. So we hope this is contributing to the scientific background of the people here. We hope to show ILSI, we hope to help for the future and maintain the visibility of ILSI and its work so that all the efforts don't get lost in all the massive amount of information that is out there. So that is basically, so what you saw it is ILSI, it is not ILSI North America, not ILSI Europe. ILSI, this is the overall umbrella organisation ILSI. Which also is the organisation that has the WHO status, that is why hosting this meeting, although in practice it was mainly ILSI North America, with help from us ILSI Europe. But that is just behind the scenes.

(Interview, November 2007)

By having observer status recognised by the WHO, ILSI can participate in the work of Codex by hosting side-events. The ILSI workshop was advertised on the official website as being held in conjunction with the 29<sup>th</sup> Session of the Nutrition Committee.

ILSI conducts much of its work through taskforces, of which the ILSI Europe Dietary Carbohydrates Task Force is one. This task force supported ILSI's work on dietary fibre. According to Pijls, taskforces involve industry sponsors, but this does not compromise the scientific work conducted:

we don't want a situation where the next taskforce starts an expert group and then, in theory, the taskforce members, the companies, say we don't really like the outcome, let's not publish this. No, we don't work like that. Once a taskforce sets up an expert group, the taskforce can see review drafts, they can give advice, but the expert group decides, you know they put in what they think should be there and we always insist on publishing whatever happens. So that is the mechanism we have in place to make sure for our reputation because many

companies they join us, and much of the work is valued because we have this, everything is transparent. Everything we do, the funding is always transparent, we always have the majority of the academic people, never dominated by the industry people and once the publication is ready, disseminated then our job is done.

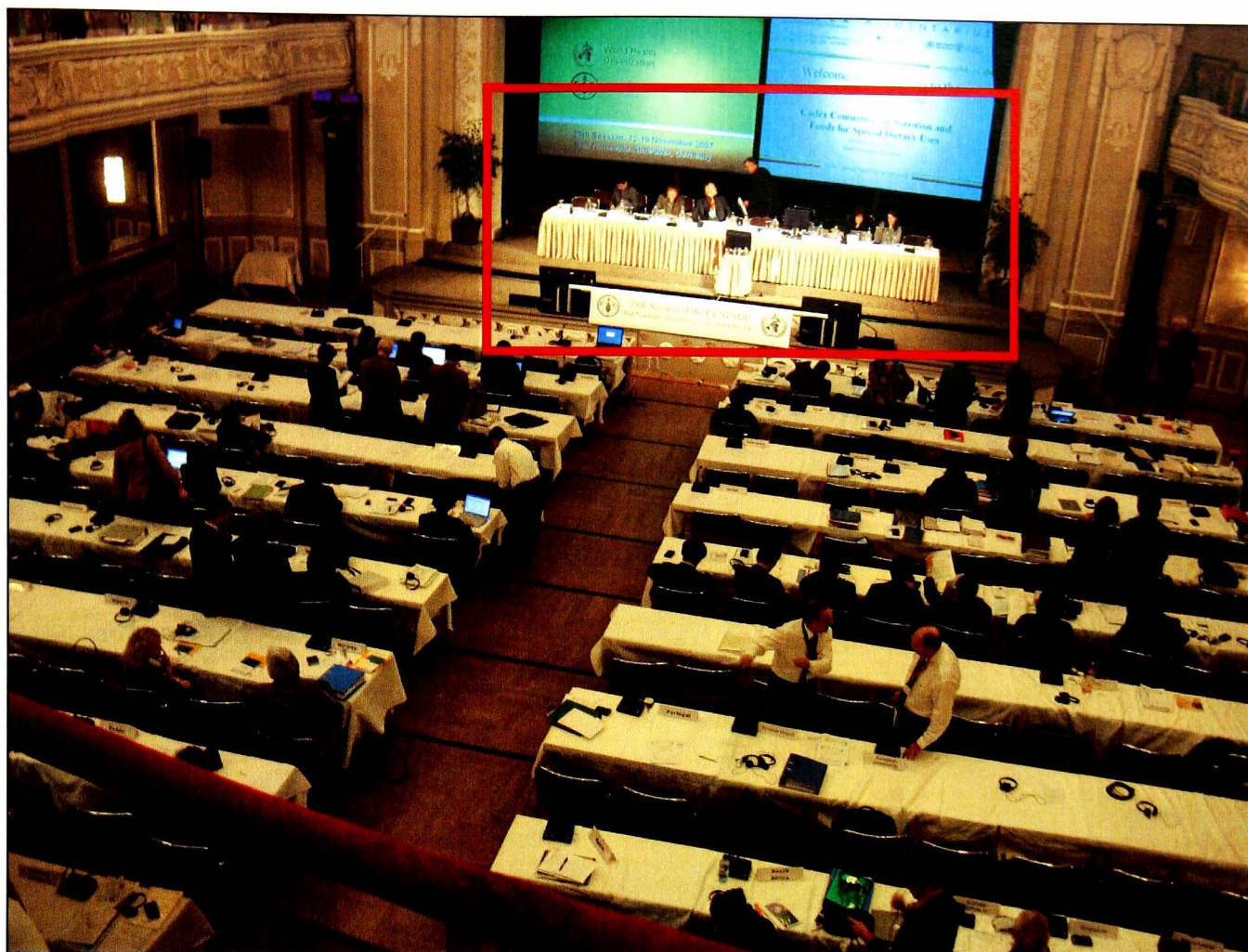
The general conclusion of the three talks given at the ILSI workshop was that the draft Codex definition to be discussed in the Nutrition Committee should be accepted by the member governments. Julie Miller Jones, while talking principally about the definition of dietary fibre, related this to the need for methods of analysis, suggesting that definitions and methods of analysis are a balancing act. She pointed to the agreement of AOAC methods as significant developments in agreeing a definition for dietary fibre, but she cautioned that definitions based on methods do not adequately deal with physiological factors. Barry McCleary focused on AOAC methods, pointing out that the Englyst method did not survive inter-laboratory studies and has not been accepted as an AOAC method. He highlighted recent work his company, Megazyme, had undertaken to develop a method for analysing 'total dietary fibre', which includes the measurement of resistant starch and non-digestible oligosaccharides. This method is subject to evaluation by the AOAC. Marcel Roberfroid concentrated on the physiological aspects of dietary fibre, suggesting that 'defining dietary fibre is still a nightmare'. He expressed support for the draft Codex definition, concluding that it allowed for different aspects of non-digestibility.

After the three talks, time was given to questions and discussion. The first question concerned the Englyst method for measuring non-starch polysaccharides. The speakers were asked how the Englyst method compared with AOAC approved methods. Barry McCleary noted that the FAO/WHO Scientific Update defined dietary fibre as intrinsic plant cell wall polysaccharides, but food intake statistics suggest that many people are not attaining their recommended intakes of dietary fibre by this definition. He stressed the need to get more fibre into the diets that people do eat, and that the Englyst method, by only measuring non-starch polysaccharides, would inhibit this. Julie Miller Jones agreed, noting that the Englyst method had not survived 'the co-labs', meaning that applications of the method across different laboratories had not produced acceptably similar results. She raised the question of oatmeal/porridge, suggesting that the gluey mass produced when porridge was heated meant that plant cell wall polysaccharides were no longer intrinsic, and so this raised problems for a narrow definition. There was

further discussion on the subject of animal sources of dietary fibre and on the inclusion of disaccharides found in breast milk. Another question was directed to Barry on the subject of applying his method. Barry stated that the method was developed to match AOAC and Codex methods, but the problem was how to deal with resistant starch. He stressed the need to analyse dietary fibre with a gravimetric technique, rather than a chemical technique as used in the Englyst method. In concluding the remarks, Julie suggested that the talks provide a clear basis for the decisions which had to be made in the Nutrition Committee.

At 12:48 the following day the Chair of the Nutrition Committee, Rolf Grossklauss, announced the opening of discussion on Agenda Item Three, 'Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B Containing Provisions on Dietary Fibre)'. He noted that the Committee had been trying to define dietary fibre since 1992. At this point the Chair wondered out loud whether there would be an opportunity to discuss the expert definition of dietary fibre. As John Cummings from the expert group was sat four seats to the Chair's left, it seemed unlikely that he would not be given the opportunity to speak to the Committee. The seating arrangement of the meeting can be seen in figure 4.2, where the red rectangle denotes the top table comprising the Chair, assistant to the Chair, Codex secretariat and FAO/WHO representatives. However, before John Cummings spoke, Chizuru Nishida from the WHO addressed the Committee. She made a number of points. Firstly, that the expert definition produced by the FAO/WHO was the result of an expert group, not an expert consultation. The work was carried out as part of a normative mandate, not a request for expert advice. Secondly that FAO/WHO were exploring the possibility of updating the last expert consultation held in 1997 (FAO, 1998). Thirdly, that she was happy to have John Cummings at the meeting to present the definition of dietary fibre first provided at the 28<sup>th</sup> Session of the Nutrition Committee in 2006.





*Figure 4.3: The Codex Nutrition Committee breaks for coffee (R P Lee)*

The presentation made by John Cummings concerned the outcomes of the FAO/WHO Scientific Update on Carbohydrates in Human Nutrition (hereafter the Scientific Update). As Chizuru Nishida suggested in introducing John Cummings to the Nutrition Committee, the Scientific Update was conducted as part of normative work. Normative work covers all the activities undertaken by FAO and WHO except technical assistance, which is described as operational work (FAO, 1998a). Later in interview Cummings spoke about the process of establishing the Scientific Update, suggesting that:

So they [FAO/WHO] said yes, we will have this as a priority. But when they came to find the money for it they couldn't get it. And so instead of having a full expert consultation, which would cost them a lot of money, they decided to have what was called a Scientific Review, as a preliminary to an expert consultation...So the organisation was stuck for funding for the review, so we did it on a small budget. But nevertheless got a very good international group of people together.

(Interview, February 2008)

John Cummings began his presentation by stating that the Scientific Update dealt with carbohydrates as a whole, not just with dietary fibre. Carbohydrates were deemed to be an important part of the diet and subject to change, with new developments around glycemic index, sugars, wholegrains and oligosaccharides. He described how innovations around ‘pre-biotics’ have brought a new dimension to discussions of dietary fibre. The difficulty with dietary fibre was in trying to characterise it. At this point Cummings referred to the definition agreed by the expert group; “Dietary fibre consists of intrinsic plant cell wall polysaccharides.” (Cummings and Stephen, 2007: S13). This is a precise definition and suggests that dietary fibre is composed of particular carbohydrates (polysaccharides) which are found in the plant cell wall. Importantly, the definition emphasises such polysaccharides are intrinsic to the cell wall, that is they cannot be regarded as dietary fibre if they have been extracted from the cell wall. The definition was published, along with all the other papers included in the Scientific Update, as a supplement in the December 2007 issue of the European Journal of Clinical Nutrition. Members of the Nutrition Committee had been privy to these papers from the 6<sup>th</sup> November, around one week before the discussion of dietary fibre.

The lunch-break was imminent as John Cummings continued his introduction to the Scientific Update. He commented on the scope of the definition, suggesting that the concept of non-digestibility had not been included in the definition of dietary fibre as this produced problems. A physiological basis for a definition could not be agreed according to Cummings and so this was not used. He remarked that non-digestibility was an elusive concept. Instead, it was better to define dietary fibre by chemistry. Cummings mentioned that some physiological claims would be more appropriate as health claims for foods, rather than as dietary fibre, and that it could be misleading to the consumer to include a range of components under dietary fibre (which is a nutritional category). The term ‘intrinsic’ was also felt to be a crucial element of the definition, and he drew attention to the use of intrinsic in IoM Report (IoM, 2002). In conclusion he said the papers have been published and circulated, they should be read and a broader view of carbohydrates taken. He felt that the food industry could still exploit innovations under health claims, rather than under the category of dietary fibre.

The intervention of John Cummings and Chizuru Nishida in the Nutrition Committee positioned the FAO/WHO Scientific Update at the centre of the debate which followed



lunch. In the official record of the meeting it is stated that the Nutrition Committee: “requested additional information regarding the work of the expert group and the issues and approaches employed by the expert group in reaching the conclusions. Therefore, WHO requested Cummings, as a member of the expert group which undertook the scientific update for FAO and WHO, to participate and further inform the Committee” (Codex, 2008). Member governments and observer groups to the Nutrition Committee had only received the published version of the Scientific Update on the 6<sup>th</sup> November, one week prior to the meeting. As a result Cummings, at the request of the WHO, was able to offer the Scientific Update as a new piece of evidence in the debate over defining dietary fibre. Prior to the Nutrition Committee, interested parties had little time to fully assess the papers comprising the report and to consider appropriate responses.

When the meeting reconvened after lunch, there was a noticeable reticence by member governments to offer comments. The Delegation of Benin did remark that animal sources of fibre, such as collagen, should be considered in the definition. The most vocal interventions came from Ibrahim Elmadfa<sup>28</sup> on behalf of the International Union of Nutritional Sciences (IUNS). He agreed with the definition of the FAO/WHO in terms of the positive effects of cell wall components and expressed concern about the scope of the current Codex definition. However, he also suggested that physiological aspects played a role and that fibre coming from oats might be excluded. The Chair addressed John Cummings directly during the pregnant pause which filled the room and asked how it is possible to distinguish between intrinsic and extrinsic plant cell wall polysaccharides? Cummings suggested that he deliberately avoided going into the method in order to clarify the definition, but that it would be possible to use an ingredient list to get quantitative identification. Cummings also returned to a point the Chair made about some elderly people not being able to eat wholegrain foods and that according to a food technologist one method of avoiding this scenario was to add synthetic dietary fibre to white bread. Cummings expressed his sorrow at hearing this, but pointed out that excluding those sources of fibre from the definition of dietary fibre did not stop foods being manipulated in this way. Instead it invoked another category of foods; those with health claims attached to them.

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<sup>28</sup> President-elect of the IUNS and Head of the Department Nutritional Sciences, University of Vienna.

The opening discussion of the Scientific Update had not involved any interventions by member governments until the issue of health claims was raised by John Cummings. In response to these comments, Basil Mathioudakis, head of the European Community Delegation, asked how you would label products comprising synthetic fibres if the definition of dietary fibre did not include them. Mathioudakis suggested there was a science and a policy aspect to the issue. Cummings stated that if, for instance, resistant starch gave a health benefit, then that evidence could be shown on the label, but that it would be misleading to claim it had the same properties as plant-cell wall polysaccharides. The reluctance of member government delegations to offer comments on the Scientific Update led the Chair to consider whether further discussion of the agenda item was necessary. He stated that he didn't see a consensus between the definition *worked out* (the Codex definition) and the new *strict* definition (the FAO/WHO definition). At this point the Chair engaged in an off-microphone discussion with Jeronimas Maskeliunas, a senior member of the Codex secretariat, and Katharina Adler, assistant to the Chair, who was responsible for typing the amendments to text as suggested by delegations. These amendments are visible to the participants on a large projector screen, as shown in figure 4.4:

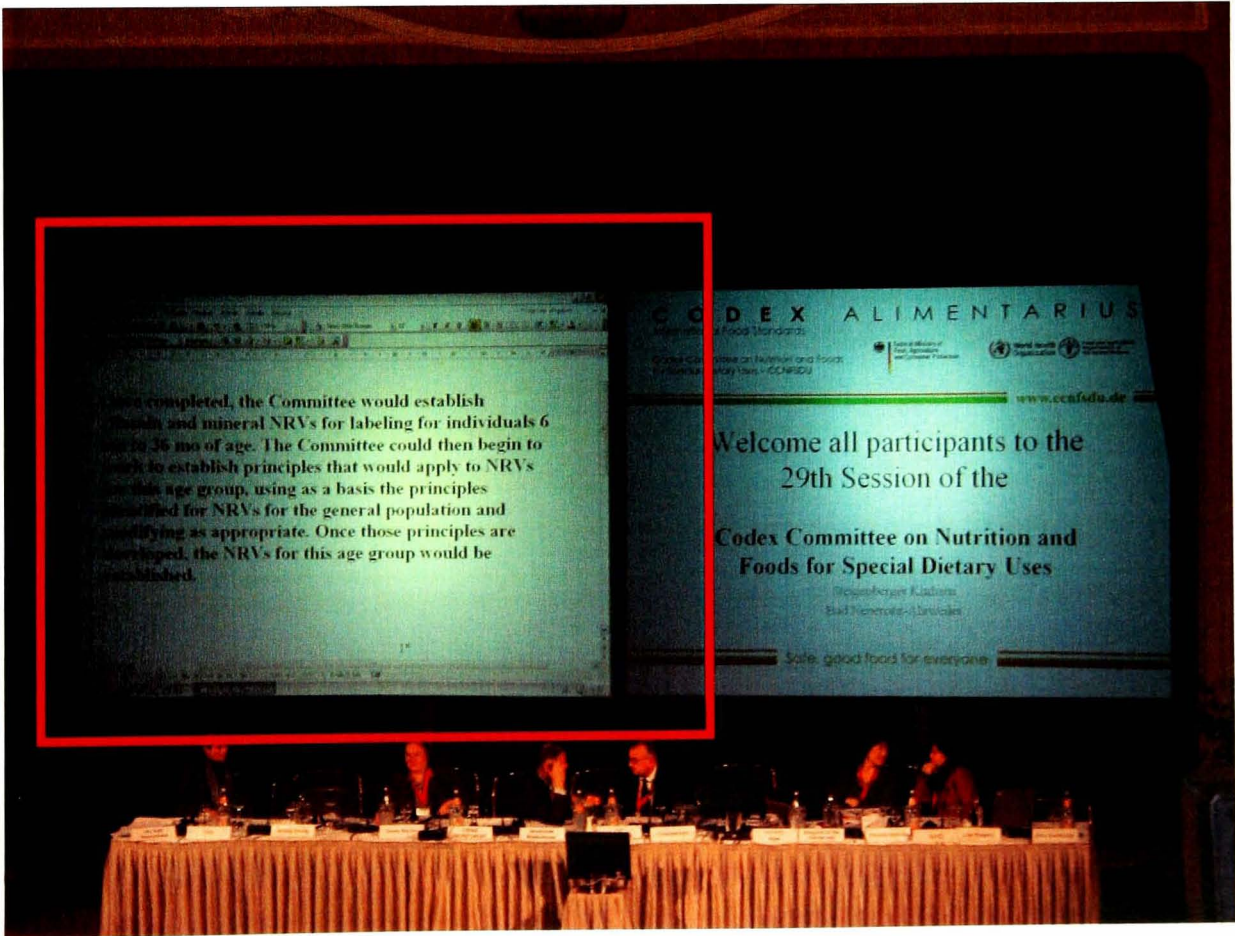


Figure 4.4: The use of a word processor to produce Codex standards (R P Lee)

Above the conversations which had broken out in the room, the Chair signalled he had seen that the Canadian delegation wished to speak. The head of the Canadian delegation, Mary l'Abbé, stated that they did not have time to review the Scientific Update and asked whether there were specific studies which were used to come up with the definition. John Cummings apologised for the short notice given, but suggested that most documents were cited in the papers. Again l'Abbé asked if there were specific studies and Cummings reiterated the references were present in the papers comprising the Scientific Update. It seemed that member governments were not able to take forward discussion, as the basis for discussion had to proceed in response to the FAO/WHO scientific advice. However, none of the member governments seemed equipped to make concrete statements given the amount of time they had spent assessing the Scientific Update. Most were unsurprised by the definition offered by the Scientific Update ("dietary fibre consists of intrinsic plant cell wall polysaccharides.") as this definition had been proposed by the FAO/WHO at the previous meeting of the Nutrition Committee held in Thailand in 2006 (Codex, 2007a). What was more difficult to deal with, given the time available, was the technical content of the papers comprising the Scientific Update.

The continued discussion of dietary fibre as an agenda item seemed to be in doubt. Indeed, the report of the meeting summarises the remaining discussion as, crudely put, 'no agreement' (Codex, 2008a). However, this does not give an accurate reflection of the discussion. As an atmosphere of impasse seemed to be filling the room, Barbara Schneeman, head of the US delegation, asked how the discussion could be taken forward. In particular she asked whether John Cummings could comment on the relationship between claims and agreeing a definition for dietary fibre. Cummings responded that claims came after an understanding of the physiology. He stated that the expert group had focused on the key principle of dietary fibre and that was how they agreed on plant cell walls. Only after that agreement could you then consider claims. Sensing the impending collapse of discussion on this agenda item, the Chair asked if it would be useful to set-up an ad-hoc working group in order to further discussion. He commented that he felt there was still a scientific definition which could be agreed but wondered if the current definition was compatible with the FAO/WHO and asserted there would be a need to distinguish between a definition important for labelling and dietary advice to consumers, in keeping with the principle of fair global trade in

foodstuffs. Basil Mathioudakis, head of the European Community Delegation, intervened again. He proposed that the suggestion of John Cummings “takes us back to where we started many years ago” and that the idea that claims should start from an understanding of the physiology was:

maybe a case of a scientist talking to a committee which takes scientific advice but eventually writes up standards for the consumer. We have to take decisions on scientific advice. This is not only FAO/WHO advice, EFSA offer totally different advice. I do not think a working group that sits down with FAO/WHO would be advancing things.

(Personal note, November 2007)

The Chair asked for further comments from other member governments in a bid to broaden and energise the discussion. However, little was forthcoming. Denis Mikode, the representative of Benin, suggested to John Cummings that he take into account comments made by the committee about finalising the work. Turid Ose of the Norwegian Delegation dampened enthusiasm for further discussion by suggesting that the member governments needed “another year back home and discuss these documents with our experts.” The Chair acknowledged that any momentum had been lost and began to talk off-microphone to Jeronimas Maskeliunas in order to agree how the agenda item should be wrapped up. The Chair then stated to the room that the agenda item will be held at Step Seven of the Codex process and that everyone should make comments on the document. Mary l’Abbé, of Canada, asked whether a circular letter would be sent out in order to clarify the task. At this point Jeronimas Maskeliunas intervened on the microphone to explain what would happen in the future. He stated that by holding the agenda item at Step Seven, no new comments would be sought, and that:

It was the Codex secretariats understanding that there was a need for member governments to look at the WHO documents and discuss within their own countries. It is a scientific paper and should stay as such. Next year we will come with the same documents. We will come with a definition at Step Seven as in the current circular letter. We will try to finalise and complete the work. How we do it will depend on the member governments.

(Personal note, November 2007)

In setting out this procedure, the Codex secretariat was referring to the uniform process for the elaboration of Codex standards as set-out in the procedural manual (Codex, 2008e). For draft standards at Step Seven of this process it is stated that “The Comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the standard.” (Codex, 2008e: 33).

Some clarification was sought by Barbara Schneeman, head of the United States delegation, as to what comments might be provided for the next meeting. She was unclear about how member governments were being asked to proceed. Jeronimas Maskeliunas restated the position. He suggested that further questions should not be asked if retained at Step Seven, so if further questions and comments were to be made the agenda item should be returned to Step Six. But that would require specifically formulated comments. The Chair intervened at this point and set out two options: keep at Step Seven or return to Step Six for further comments. The member governments seemed confused by the instructions given by the Codex secretariat and the Chair. In response, Basil Mathioudakis asked the Codex Secretariat for advice as to whether member governments would return to discuss the same item in light of the Scientific Update if the agenda item were to remain at Step Seven. If this were the case, he suggested that member governments will have a position for the meeting and that this position should be made explicit in advance in order to facilitate discussion. The concern of Mathioudakis was for the comments by member governments to be made available before the meeting in 2008. From the Codex Secretariat, Jeronimas Maskeliunas responded by stating the only way to make positions explicit was to return the agenda item to Step Six. Comments would then have to be submitted well in advance. He pointed out that the German secretariat (to the Nutrition Committee) would prepare the comments paper and that this would be completely in-keeping with Codex procedure. If the item were to remain at Step Seven then no comments would be recorded. In a final intervention the Chair thanked the Codex secretariat for the clarification. He noted the limited time available to read and discuss the document and so proposed that the agenda item be returned to Step Six for further comments. He thanked John Cummings, stated he was optimistic all would be agreed next year and closed the agenda item.



## 4.4 Making Comments in Codex

The previous section comprised an account of some of the activities which were conducted in order to agree (or fail to agree) on a definition for dietary fibre and a method of analysis. Many more activities took place during and prior to the week of the Nutrition Committee meeting in 2007. For instance, in the foyer of the hotel hosting the majority of the Codex delegates and side-events, a board detailed the time and location of co-ordination meetings with the Chair for member governments and between regional blocs, such as the EU member states and the European Commission representatives and the Quad countries, closely following the trade blocs identified by Veggeland and Borgen (2005) as having an increasing significance in the Codex post-WTO. I had no access to these co-ordination meetings, which were held between the relevant member governments. However, other meetings and discussions were held throughout the host town; in coffee shops, over lunch and at evening dinners. Coffee breaks in between the discussions at the Nutrition Committee were usually used as a trigger for further informal discussions between delegations. I had access to some of these conversations. Given the frequency of discussions and meetings held formally and informally, it is impossible to give a truly all encompassing analysis of the process, even for a government delegate.

While much discussion takes place in and around the committee meeting, the Codex process involves other negotiation mechanisms. One overt activity which interested parties engage in is the submission of comments in advance of Codex meetings (as emphasised by Basil Mathioudakis in the previous section). These comments provide an important source of information on the actors interested in negotiating the final form of Codex standards and on the substance of the technical debates. Since 2000, seventy-nine comments on the issue of dietary fibre have been received by the Nutrition Committee secretariat, with member governments submitting fifty-two comments and observer groups twenty-seven. No comments were submitted during 2002 or 2003 while a discussion paper on dietary fibre was in preparation and national sources of evidence were forthcoming (Codex, 2003a; 2004b). The submission of comments is an important part of the Codex standard-setting process and is mediated by the Codex uniform process for elaborating standards, as detailed in Chapter Three. The Codex Claims standard was initially put forward by the Codex Co-ordinating Committee for

North America and South West Pacific and agreed by the Executive Committee of the Codex Alimentarius Committee (hereafter the Executive Committee). On this matter it was reported that the Executive Committee “agreed to endorse the elaboration of Codex General Guidelines on Nutrition and Health Claims for Labelling through the Codex Food Labelling Committee, with the understanding that the issue of advertising would be limited to discussions only. It was noted that work on European Commission Directives in the areas of health and nutrition claims would be reported to or part of its discussion on this matter.” (Codex, 1991b).

At Step Two of the standard-setting process, a ‘proposed draft standard’ is prepared. As was discussed in Section 4.2, Canada submitted this to the 1991 meeting of the Codex Food Labelling Committee. It is from Step Three onwards that interested parties are asked for their comments, “including possible implications of the proposed draft standard for their economic interests” (Codex, 2007). At Step Four the comments are considered by the subsidiary committee and the proposed draft standard can be amended. When a proposed draft standard is advanced to Step Five, the Secretariat submit it to the Executive Committee for critical review in order to decide whether the standard can be become a ‘draft standard’. At Step Six, the draft standard is sent for further comments by interested parties. At Step Seven the comments received by the Secretariat are then consider by the appropriate subsidiary body. The final stage of the adoption process is Step Eight in which the draft standard is submitted to the Executive Committee for critical review and to the Codex Commission, along with any further comments received. The Codex Commission then takes a decision on whether to adopt the standard.

The adoption of standards by the Codex Commission at Step Eight is often a smooth process, as noted in Chapter Three. Should detailed discussions of a draft standard occur in the Commission, the Chairperson will attempt to close debate down. This process is acknowledged by delegates, for instance, in the 2007 meeting of the Codex Commission, a standard on the maximum levels of tin in canned foods drew comment from the EU delegation over concerns that the maximum levels were too high. However, the delegation stated that they “do not propose to block, but would like our concerns to be noted” (Personal note, July 2007). When a standard reaches Step Eight

and is advanced to the Codex Commission it is almost certain to be adopted, even if there is strong disagreement by some member governments.

In the case of the Claims Standard, the table for nutrient descriptors was adopted in a piecemeal fashion and did not pass smoothly through the Codex Commission. Part A of the Table (without dietary fibre) was adopted at the 22<sup>nd</sup> Session in 1997 with relatively little problem. Part B of the Table (without dietary fibre) was not adopted, but instead, unusually, was returned to Step Six for further discussion in the Nutrition Committee. This delay was not repeated at the following session of the Codex Commission in 2001, and the Table was adopted. The provision of dietary fibre had not been recommended for adoption at any stage and remained in circulation at Step Six of the procedure, allowing for further discussions and comments in the Nutrition Committee. The process of submitting comments to the Nutrition Committee remained an important activity for the elaboration of a definition for dietary fibre and method of analysis. At the end of the 2007 meeting of the Nutrition Committee the remaining element of the Claims Standard – the definition of dietary fibre – had moved from Step Seven to Step Six. Step Six allows comments on all aspects of the draft standard, whilst Step Seven requires comments to be considered by the Nutrition Committee. Since 2000 these provisions on dietary fibre had oscillated between Step Six and Step Seven, and in doing so attracted comments year on year.

Seventy-nine comments were received on the provisions for dietary fibre between 2000 and 2008. Australia provided detailed comments at every opportunity during this period, the only member government to do so. The comments submitted by Australia in 2008 refer directly to the FAO/ WHO Scientific Update discussed in previous sections of this Chapter, stating that the definition of dietary fibre put forward in the Scientific Update:

has major ramifications for many regulatory systems around the world which currently use a broader definition. Regulatory systems do not operate separately; they need to reflect current national decisions about the definition of fibre underpinning fibre content values that then are used to estimate fibre intakes and establish reference health values, which in turn can be incorporated into nutrition labelling.

(Codex, 2008b)



The comments of Australia expressed strong disagreement with the definition proposed by the Scientific Update of the FAO/WHO, suggesting that the draft Codex provisions on dietary fibre to be ‘more appropriate for food regulatory purposes’. In contrast, New Zealand, as one of the member governments providing the second greatest number of comments on this issue, took a different stance. Rather than critiquing the Scientific Update, New Zealand expressed agreement with the recommendation that there was no scientific evidence to support claims that non-plant based dietary fibres could reduce chronic disease. In addition New Zealand suggested that the Englyst method of analysis for dietary fibre should be added to the list of permitted methods. Brazil, another regular commentator on the provision on dietary fibre, went further, stating that:

Brazil agrees with the adoption of the FAO/OMS definition for dietary fibre: intrinsic plant cell-wall polysaccharides.

(Codex, 2008c)

The FAO/WHO Scientific Update had successfully altered the terms of discussion upon which interested parties could put forward their positions. The controversy over the provision of scientific advice to the Nutrition Committee, and the implications of this for international standard-setting, will be dealt with in Chapter Six. The intention in this chapter has been to detail the activities which have been conducted in an attempt to meet the mandate prescribed to the Nutrition Committee by the Food Labelling Committee in 1992. This mandate was to produce values to complete the ‘Table of Conditions for Nutrient Descriptors’ as part of the Codex Claims Standard.

## 4.5 Conclusions

This Chapter has set out some of the standard-setting activities conducted in order to agree a definition for dietary fibre in the Codex system. In Section 4.1 the growth of investment by food companies in the area of functional foods was discussed, in particular the interest in developing ‘gut health technologies’. The drive to expand nutritional and health claims for a greater variety of food products has been a significant pressure upon regulatory approaches to such claims. In this context, standard-setting has been strongly influenced by innovations within the food industry. The scope and content of a definition for dietary fibre was detailed in Section 4.2, with reference to

negotiation held in the Codex system from 1992 until 2002. During this period, there was not a significant controversy over dietary fibre, as the Nutrition Committee was mandated by the Food Labelling Committee to produce values for all nutrient descriptors which could be used to complete their work on the Codex Claims standard. In part this work was completed, as values were submitted for energy, fat, saturated fat, cholesterol, sugar, sodium, protein and vitamins and minerals, and were subsequently adopted by the Codex Commission. The values for dietary fibre remained open for discussion, as no agreement could be reached on an appropriate definition for dietary fibre and on the methods of analysis for identifying dietary fibre. The table of conditions, which formed part of the Codex Claims standard, had to be split in order for one part to be agreed. The second part of the Table was only partly agreed, with values for protein and vitamins and minerals sent to the Codex Commission for adoption, whilst dietary fibre remained on the agenda of the Nutrition Committee. As disagreement over the provision on dietary fibre began to surface, member governments, notably the United States and Sweden, highlighted work which they were undertaking within their own regulatory systems on the issue. National levels of activity began to directly feed into the Codex process as reports were forthcoming. At the same time, the Nutrition Committee initiated a working group in order to produce a definition and method of analysis for dietary fibre. The working group produced a report in September 2003 which formed the blueprint for the draft provisions still being debated in the Nutrition Committee. The Codex definition is contradicted by the FAO/WHO Scientific Update.

The remainder of this Chapter dealt with various activities which comprise standard-setting in Codex, namely discussions in the committees, discussion outside of the committees and the submission of comments in advance of meetings. Analysis of these processes will be advanced in Chapter Six. For now it is possible to say that the 2007 Nutrition Committee meeting, and in particular the discussion (or lack of discussion) on dietary fibre, was produced by the mediation of Codex processes by prominent actors. The scientific advice presented by John Cummings was not as surprising to participants as the recommendations of the expert group involved in the FAO/WHO Scientific Update had been made public in 2006. What had been delayed was the technical content of the arguments used to support the recommendations. The short period of time available to address these issues seriously constrained the ability of participants in

the Nutrition Committee to discuss the future direction of the provision on dietary fibre, as any discussion would have to refer to the advice being offered by FAO/WHO. Other activities took place to counteract the expected presentation of the Scientific Update, notably the workshop hosted by ILSI. The workshop was legitimised by having close affiliation with the workings of the Nutrition Committee and invitations were extended to all member government delegates. A unified argument was presented by three scientists each dealing with a specific aspect supporting the current Codex provisions for dietary fibre. Ultimately these efforts were derailed by the limited possibilities for member governments to respond to the Scientific Update.

In considering the trajectory of scientific debate, Latour (1987) has suggested that when technical documents begin to accumulate this is usually an indication that the issue in question is becoming more controversial. The scientific papers comprising the Scientific Update are a good example of what Latour (1987) calls ‘rhetorical vehicles’; that is a medium through which argument and persuasion takes place. In order to make the arguments more powerful and persuasion more likely, scientific papers can adopt three tactics. They can enrol friends into the argument being made, they can refer to other, supportive texts and they can be referred to positively by other texts. The adoption of these tactics in the Scientific Update meant that member governments could not easily judge the implications of the rhetorical strategies employed, given the time available.

Having detailed the activities which took place in and around the Nutrition Committee, the submission of comments as important elements of the standard-setting process in Codex was discussed. Comments, however, do not reveal everything about the arguments and positions of interested parties. Some actors do not post comments even though they are heavily involved in the debate. For instance, it was not possible for the EU delegation to submit comments as – at that point in time – there was not an agreed position amongst EU member states and the European Commission. Despite this, comments do reveal lines of argument and give crucial weight to points being discussed in committees. It is easier for a member government or observer group to make an impact in discussion if they have made specific comments in advance.

The following Chapter makes a partial retreat from the world of Codex standard-setting. Instead, the Chapter examines how the science of dietary fibre first emerged, in order to provide a background to the regulatory debate and to reveal how the concept of dietary fibre has been developed over the last forty years. If scientific and technological developments are constituents of the political process, as will be argued in Chapter Six, then it is crucial that these developments are taken seriously and are afforded detailed analysis. The sequencing of these Chapters is a deliberate attempt to ensure that technical concepts are not introduced too early into the analysis and to provide an account which demonstrates the interplay between regulatory and scientific domains.<sup>29</sup> A full discussion of the implications of Chapters Four, Five and Six will be undertaken in Chapter Seven.

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<sup>29</sup> It also reflects the sequencing of my investigation, which firstly involved an immersion into the regulatory domain and was preceded by a focus upon on scientific activity.

## Chapter Five – The History of Dietary Fibre Science and Technology

### 5.1 Introduction

As demonstrated in Chapter Four, defining dietary fibre has proved to be a contentious activity in the Codex. The contention has not been confined to the regulatory domain, as disagreement and tension have characterised the scientific debate over dietary fibre. A settled definition of dietary fibre and an appropriate method of analysis cannot be agreed amongst the scientific community or between government regulators. The Codex standard-setting procedure has been initiated to provide an internationally agreed definition, one that will form the basis for dietary fibre claims on internationally traded food products. In this Chapter, the origins and trajectory of disagreements over dietary fibre amongst scientists are analysed. The account draws upon observations, interviews, scientific publications, minutes from meetings, advertisements and popular writing. The Chapter demonstrates how regulatory contention in the Codex over the definition of dietary fibre is pre-dated by disagreement amongst scientists and technologists. In particular, the importance of a core-set of scientists (Collins, 1981) to the on-going scientific controversy over dietary fibre is demonstrated. The core-set are those scientists most closely involved in a scientific controversy. A primary characteristic of the core-set is the limited number of interactions between core-set scientists who are in disagreement.

Section 5.2 deals with the emergence of dietary fibre as a concept during the 1970s. The section focuses upon how the dietary fibre paradigm emerged primarily through the work of Hugh Trowell and Denis Burkitt. It was their work on dietary fibre which set the association between dietary fibre and plant-based diets. Trowell has described dietary fibre as a paradigm (Trowell, 1985), even applying the notion of scientific paradigms as used by Kuhn (1962/1996). However, the discovery of dietary fibre and the construction of the dietary fibre paradigm provoked further research on the chemical and physiological aspects of this group of carbohydrates. During the late 1970s and 1980s attempts to define and measure dietary fibre meant that new and varied interpretations of dietary fibre were made possible. The application of analytical

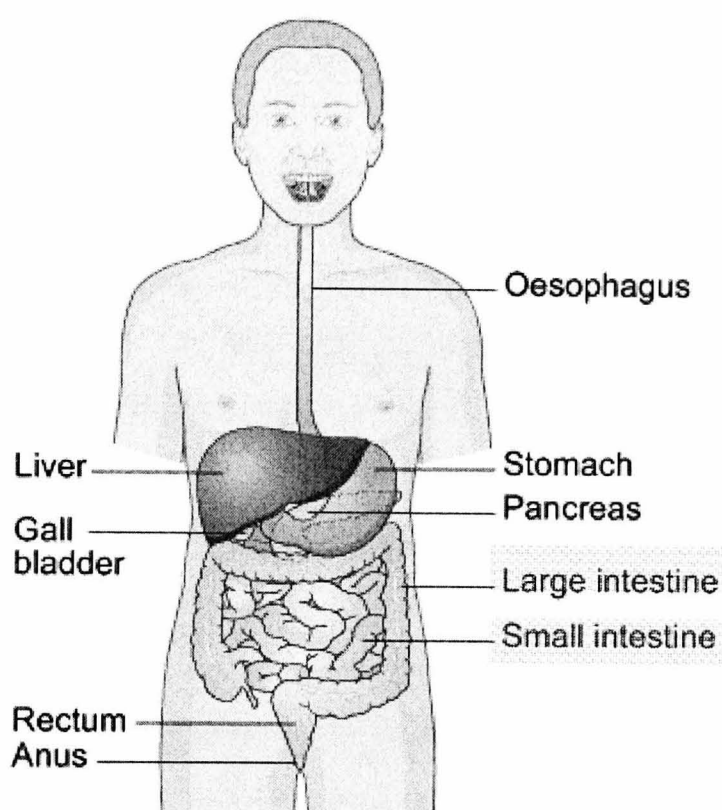
techniques to the substances comprising dietary fibre led to divergence in the science of dietary fibre.

The consequences of increased scientific activity for the dietary fibre paradigm are explored in Section 5.3. Dietary fibre enters public awareness as the benefits of a high-fibre diet are extolled by food companies, food writers and scientists. At the same time, the science of dietary fibre becomes increasingly fraught with tensions. Attempts to arrive at a common definition within Europe were undermined by diverse methods of analysis, which in turn were premised upon different notions of dietary fibre. Section 5.4 charts the spiralling scientific contention over dietary fibre from the 1990s onwards. In particular the confluence between scientific dispute, technological developments and regulatory negotiations are noted. The Chapter concludes by considering the changing nature of dietary fibre science and technology and the potential consequences of this for standard-setting.

By way of introduction to the history of dietary fibre science, it is helpful to review some basic concepts in human nutrition. Foodstuffs can be described according to their constituent nutritional components. The most commonly identified nutritional components in foods are termed macronutrients. Macronutrients include carbohydrates, fats, and proteins. Dietary fibre is a term used to describe a kind of carbohydrate. Carbohydrates are produced by plants during photosynthesis and are normally grouped into three categories: polysaccharides, oligosaccharides and sugars (mono- or disaccharides). According to Asp and Bender (2005), the most important method of classifying carbohydrates is between those which are digested and absorbed within the small intestine and those which pass through to the large intestine. Defining dietary fibre on the basis of digestibility is contentious and, as will be discussed later, includes a diversity of food components as dietary fibre.

The digestion of food by humans occurs in the gastrointestinal tract which runs from the mouth to the anus. Figure 5.1 shows the basic digestive system. Two zones of the gastrointestinal tract are of particular relevance to any discussion of dietary fibre: the small intestine and the large intestine (comprising the caecum, colon and rectum). The absorption of carbohydrates, proteins, fats and minerals occurs principally in the small intestine. Dietary fibre is not digested in the small intestine (though it may be soluble)

and instead passes to the colon of the large intestine for digestion. Because of this, dietary fibre is a term applied to those carbohydrates said to be ‘unavailable’, in that they remain undigested in the small intestine. A paper authored by McCance and Lawrence (1929) titled ‘The Carbohydrate Contents of Food’ and published as a Medical Research Council Special Report identified the existence of two types of carbohydrates: available and unavailable. Available carbohydrates were those that could be digested in the small intestine, whilst unavailable carbohydrates could not be digested and passed through to the large intestine.



*Figure 5.1: Basic human digestive system (UK National Health Service, 2008)*

Dietary fibre can also be classified by solubility in water. Soluble dietary fibre can be more easily fermented than insoluble dietary fibre and, it is claimed, can assist in digestion and absorption processes within the small intestine. Insoluble dietary fibre is more resistant to fermentation and binds water in the large intestine, providing faecal bulk. Soluble dietary fibre is present in higher amounts in fruits and vegetables, whilst insoluble dietary fibre is present in breads and cereals. The properties of soluble and insoluble dietary fibre align with the nutrition and health claims made about them. For instance, dietary fibre is often termed roughage and is associated with the increase in bulk size of faeces and the reduction in transit time taken for faeces to be excreted. This

is captured by the expression that dietary fibre ‘keeps you regular’ and is an outcome associated with insoluble dietary fibre as found in bran and wholemeal bread. In the case of soluble fibre, health and nutrition claims are being made in connection with cancer reduction and lowering the risk of heart disease.

The division between digestible and non-digestible (or resistant) carbohydrates is a longstanding one within nutrition science. The current disagreement over dietary fibre turns upon the importance of non-digestibility in the large intestine as a defining factor for classifying something as dietary fibre. Much of the controversy over the definition of dietary fibre has occurred because of the amount of emphasis placed upon non-digestibility in the small intestine as a defining characteristic of dietary fibre. The early definitions of dietary fibre equated dietary fibre with undigested material from the plant-cell wall. Therefore dietary fibre could only be found in plant-based foods such as fruits, vegetables and wholegrains. Developments in food science and technology have allowed for a greater range of carbohydrates which are not digestible in the small intestine. Advances in nutrition science have also begun to associate dietary fibre with wider health benefits. The debate over dietary fibre reveals a tension between the appropriate definition of dietary fibre and established categories used in food and nutrition science. Scientific disagreement over the concept of dietary fibre has been noted by Sibbel (2008) who uses the case of dietary fibre to explore the problems associated with providing nutrition advice. She suggests that dietary fibre is still an emerging concept, despite over forty years of research, and one that is characterised by “equivocal science” (Sibbel, 2008: 245).

## 5.2 Discovering Dietary Fibre

The science comprising the dietary fibre concept was not always so equivocal, as the initial elaboration of the concept centred on the work of a small group of doctors and scientists. In the opening chapter to a major edited volume on dietary fibre, Hugh Trowell describes the emergence of the dietary fibre concept as a new scientific paradigm (Trowell, 1985). In doing so, Trowell references Kuhn (1962/1996) and in particular the assertion that new scientific paradigms emerge from the activities of a group of adherents to the new concept and that this group find new problems emerge



from the delineation of the new concept.<sup>30</sup> Trowell (1985) suggests that a small group of doctors helped to produce the concept of dietary fibre in the 1970s. He includes in this group himself, Denis Burkitt, T. L. Cleave, Sir Richard Doll, David Southgate, Kenneth Heaton, Sir Francis Avery Jones and John Cummings (who presented the FAO/WHO Scientific Update to the Codex Nutrition Committee, as detailed in Chapter Four). Before elaborating on the work of this group in the formation of this new scientific paradigm, Trowell (1985) identifies five distinct areas of investigation which were to eventually combine to produce the dietary fibre paradigm. These areas were: research on fibre-rich bran in the US and UK in the 1920s and 1930s; attempts to analyse crude fibre content of high-fibre National flour, used due to shortages of wheat import to the UK during World War II; studies on the Westernisation of diets amongst indigenous South Africans; studies of diseases – such as colon cancer and diabetes – more prevalent in developed countries; work on saccharine disease, said to be the result of consuming refined and concentrated carbohydrates. Insights from these areas produced what Trowell (1985) terms the mainstream dietary fibre concept.

The discovery of the dietary fibre concept began in the early 1970s and was not marked by a single breakthrough, but instead involved the gradual establishment of a nutritional concept. Trowell and Denis Burkitt (dubbed ‘The Fibre Man’ in a biography by Brian Kellock (Kellock, 1985)), were the main pioneers. Their work on dietary fibre led to them being described as the two ‘evangelists’ of dietary fibre (Southgate, 1982) and as pursuers of ‘social medicine’ in the public interest (Lang and Heasman, 2004). Burkitt, a surgeon by profession, began working on the question of dietary fibre in 1966 at the Medical Research Council, having spent the previous decade investigating facial tumours in Western Africa alongside his surgical work.<sup>31</sup> In 1969, a paper by Burkitt was published in the *Lancet* on the subject of the epidemiology of large-bowel disease. Burkitt (1969: 1230) postulated that: “Stool bulk and content, bacterial flora, total transit time and intra-lumen pressures can all be profoundly altered by changes in diet, and in particular by the removing of the unabsorbable fibre as in much modern food processing.” In 1971, a further paper was published in the journal *Cancer* (Burkitt, 1971). Here, Burkitt produced a diagrammatic representation of the possible

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<sup>30</sup> Trowell credits the sociologist of science David Bloor with recognising the relevancy of Kuhn to his account.

<sup>31</sup> Burkitt’s lymphoma was named after this research.

relationship between diet and cancer of the bowel through reference to “little processed” and “highly processed” foods, as shown in figure 5.2:

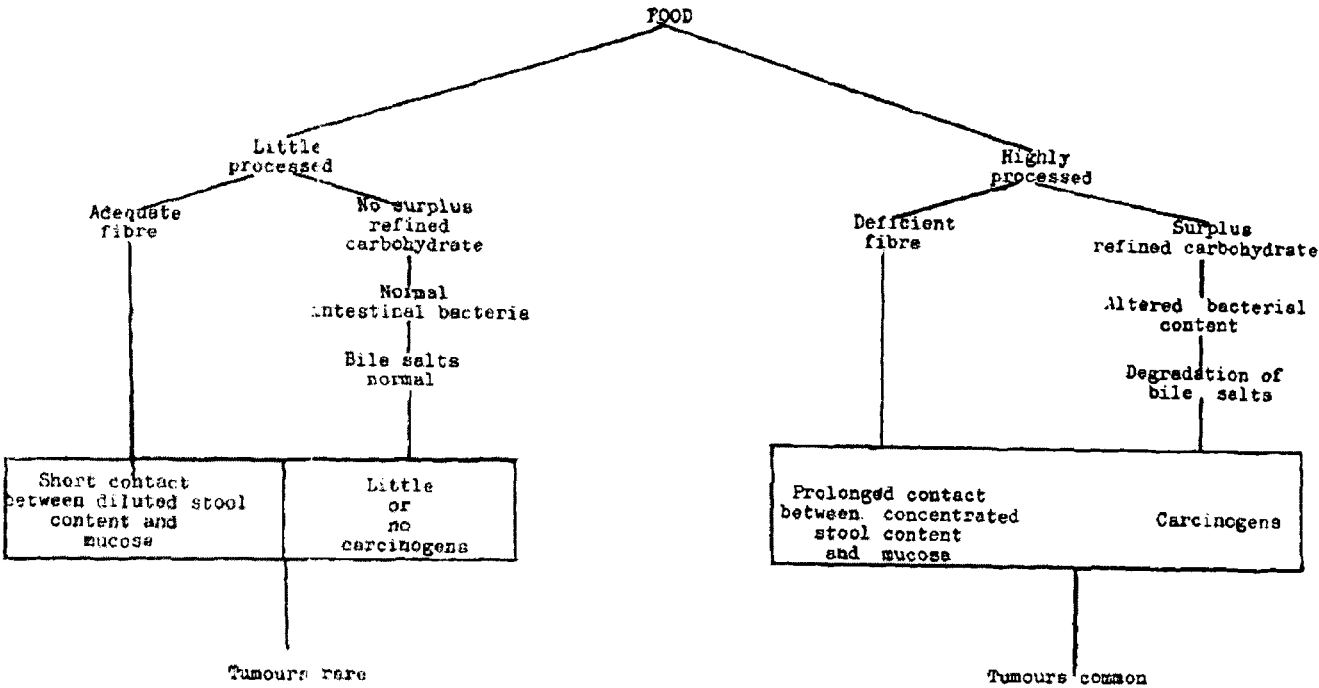


Figure 5.2: Proposed relationship between cancer and processed foods  
(Burkitt, 1971: 11)

He concluded that the removal of unabsorbable fibre from the diet and the over-ingestion of refined carbohydrates produced in food processing ought to be addressed given the relationship between certain bowel diseases and diet. The notion of processed foods being deficient in fibre, and therefore less nutritious, was an important one in the dietary fibre concept. Unprocessed or lightly processed foods, such as fruits and wholegrains, were considered to have beneficial properties and so the dietary fibre concept was premised upon a high intake of these food types.

The advancement of the concept of dietary fibre by Burkitt and Trowell had to contend with an older concept of crude fibre. Crude fibre was first identified using the Weende method and measured the indigestible components food. It is widely applied to animal feed and involves the use of acids and alkalines to hydrolyse plant cells. The material that remains from this process is termed crude fibre. In 1974 Trowell had a letter to the editor of the Lancet published, titled “Definitions of Fibre” (Trowell, 1974). In this piece he drew attention to the difference between dietary fibre and crude fibre. Trowell described how at a recent ‘Carbohydrate Workshop’ held by the National Institute for

Health in the US, nobody defended the concept of crude fibre. Trowell (1974: 503) suggested that crude fibre was defined by the Association of Analytical Communities (AOAC) as “the portion of plant food resistant to hydrolysis by acid and subsequently by alkali.” He suggested that three principal substances could be considered as dietary fibre: structural polysaccharides, lignins and unavailable lipids. Nothing else ought to be regarded as dietary fibre. In a subsequent letter to the *Lancet*, Trowell and colleagues suggest a revised definition for dietary fibre, “the plant polysaccharides and lignin which are resistant to hydrolysis by the digestive enzymes” (Trowell *et al*, 1976: 967). Significantly this definition began to engage with a chemical definition of the concept of dietary fibre, marking a new phase in the dietary fibre concept. The initial work conducted on dietary fibre by Burkitt, Trowell and other members of their surgical/epidemiological group was conducted independently of other scientific activity being undertaken on the chemistry and physiology of food carbohydrates generally. With a growing interest in the composition of dietary fibre, this situation would change.

Prominent amongst those who began undertaking work on dietary fibre from a chemical and analytical perspective was David Southgate. Southgate was working at the Dunn Nutritional Laboratory (now MRC Dunn Human Nutrition Unit), a Medical Research Council institution based at the University of Cambridge. The chemical analytical approach of Southgate required a definition in order for chemical analysis to be conducted. Here Southgate draws attention to the difference between what can be distinguished analytically and the intent of the dietary fibre concept. He suggests that:

When the diet consists of processed foods a range of non-glucan-polysaccharides may be present...In many cases they are structurally similar to components of the plant cell wall and are virtually impossible to distinguish analytically; therefore it is reasonable to regard them as part of the total dietary fibre. Individually, however, these polysaccharides are not dietary fibres and in this I support one basic thesis of Trowell *et al* (1978).

(Southgate, 1982: 3-4)

In this piece Southgate highlighted the tension between a principle of the dietary concept (material from the plant cell wall), types of diet consisting of a high intake of plant cell wall material, and the analytical possibilities of distinguishing between the components of plant cell walls and other material found in processed foods. Non-

glucan-polysaccharides include guar gum and algal polysaccharides and may be added to food products for their properties in the manufacturing process. In attempting to develop an analytical approach to measuring dietary fibre, Southgate recognised the problems of distinguishing between components considered as dietary fibre and those not. The analytical problem of identifying and measuring food components suggests that the concept of dietary fibre may have limits. As a concept, dietary fibre encapsulates the recognition of the benefits of a type of diet; one that is rich in plant cell wall material (Southgate, 1982).

The development and application of analytical methods to the measurement of dietary fibre provoked new questions of how dietary fibre ought to be defined. Developing analytical methods became a new area of contention in the dietary fibre concept as it directly corresponded to the definition. In 1977 and 1978 the European Commission organised meetings in Lyon and Cambridge respectively, in order to bring together the latest thinking on dietary fibre analysis and establish an agreed method. According to John Cummings, who participated in the Cambridge meeting:

I said that what we needed was an exact chemical measurement of the non-starch polysaccharides. That is in there on page 259<sup>32</sup>. And that started a debate which is still on-going because the method we proposed, which was an accurate method and which we have used ever since, it has been adopted very widely in the scientific world, didn't suit the food industry and particularly didn't suit the Kellogg company because it gave lower values for dietary fibre in its cornflakes than the method they were using.

(Interview, February 2008)

Another expert on dietary fibre, Nils-Georg Asp, also recognises these meetings as marking the beginning of the controversy:

It was, let me see, I think the first conference was at Cambridge in 1978 I think, where these different views were discussed. And there were several, in many nutrition conferences, around the world this became an issue that was discussed and it turned out to become difficult to find an agreement between these two, say, points of view. And I think that is the basis for the controversy that has come up on the Codex level again, now.

(Interview, August 2008)

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<sup>32</sup> Proceedings published as James and Theander (1981).

The pursuit of an analytical method by which to measure dietary fibre meant that a number of distinct groups began work on distinct methods during the late 1970s and early 1980s. According to DeVries (2003), the most significant scientific teams working on analytical methods were: Asp and colleagues (Sweden), Theander and Aman (Sweden), Van Soest and colleagues (US), Schweizer and Wursch (Switzerland) and Southgate (UK). A notable omission from the account by DeVries (2003) was work by Englyst, Cummings and colleagues in the UK. In contrast, Southgate (1995) has suggested that two major groups of methods emerged: methods to measure total dietary fibre and methods to measure non-starch polysaccharides. The Englyst group operated firmly within the 'non-starch polysaccharide' (NSP) group identified by Southgate (1995). In basic terms, non-starch polysaccharides, as a category of food components, are those polysaccharides found in plant cell walls which are not starches. Starch polysaccharides were included in the approach of the 'total dietary fibre' group (TDF). The TDF group included Asp and colleagues, Schweizer, Prosky and DeVries. Both groups of methods, NSP and TDF, began develop as distinct approaches during the 1980s.

### 5.3 Defining Dietary Fibre

By the beginning of the 1980s the term dietary fibre was not only a scientific concept, but one that had begun to enter public consciousness. Food companies extolled the virtues of fibre in relation to their food products and popular food writers enthused about the role of fibre in a healthy diet. Dietary fibre thus became part of common knowledge about food. Speaking about the usefulness of the term dietary fibre, Marcel Roberfroid, a dietary fibre scientist and ex-President of ILSI Europe, suggests that:

the problem is that if we should start from scratch now and knowing nothing about dietary fibre I would never suggest the word dietary fibre. The problem is that this word is used for about 40 years now and it has become even popular for the consumer. So if we say now, ok forget about dietary fibre, call them colonic food or whatever, it will be very difficult. And second aspect is that, dietary fibre is used for nutrition labelling. Thus probably again do we have to keep the word because it is there and is very popular and very common. But if we have to use that word then we have to define them clearly and not restrictively.

(Interview, April 2008)

Roberfroid suggests that popularity of dietary fibre means that, regardless of the perspective of scientists involved in dietary fibre science, the term has to be retained. The widespread use of the term fibre in relation to diet began during the late 1970s, meaning scientists were no longer the only people discussing the concept. In the UK, the diet writer Audrey Eyton popularised dietary fibre with her “F-Plan Diet”, published in 1982. Eyton states that:

Now, for the first time in the history of medical science, a substance has been isolated about which it is possible to say: ‘If you base your slimming diet on this food you should shed weight more quickly and easily than on a diet based on the same quantity of any other foods.’ The substance is dietary fibre.

(Eyton, 1982: 9)

Eyton goes on to cite the recommendation of the UK Royal College of Physicians (1980) that sugars and starches taken in a natural fibre-rich form could help to control obesity. She recognises work on the science of dietary fibre led to it emerging first into discussion about health and then into discussions about weight-loss. In attempting to answer the question, “What (and where) is dietary fibre?”, Eyton does not give a rigid definition but suggests that dietary fibre is the cell-wall material of plants and associated substances, while also noting that it could be considered as the carbohydrate material present in plants which is not digested. Despite providing a loose definition of dietary fibre, Eyton’s book features a table giving the fibre content of those foods with the highest amounts in a normal serving. These tables were prepared by Derek Miller, a nutritionist at University College London, though no description of the method or data used to compile the tables is included. In the tables, baked beans were ranked first, followed by Prewett’s Bran Muesli and two products manufactured by Kellogg’s: Bran Buds and All-Bran (Eyton, 1982). Having food products well-placed in these fibre tables was an undoubted coup for the featured food companies. However, food companies were already well aware of the possibilities offered by the fibre concept in marketing and selling their products. An advertisement released in the US in 1976 by Kellogg’s extolled the virtues of Bran Buds and All-Bran, suggesting that: “If you’re concerned about food fibre and your health, consider adding Kellogg’s fibre-rich cereal to your diet. They have an honest wheat taste that stays crunchy in milk.” (Kellogg’s, 1976).

Although the concept of dietary fibre had become established in popular conceptions of food and nutrition, scientists continued to explore what substances constituted dietary fibre and attempted to better understand their role in the human body. The focus of much work was upon establishing methods to measure the components present in dietary fibre and the physiological effects they had. In order to do this, methods were required which could isolate those compounds from the foods in which they were found. As suggested in the previous section, various groupings had begun to form in the field of dietary fibre science. The meetings organised by the European Commission in 1977 and 1978 revealed a tension between these groupings in respect of their approach to the dietary fibre concept and in their understanding of the appropriate method for measuring dietary fibre. Thus dietary fibre, while becoming a term known by the public and used by food companies, became more contested and disputed amongst scientific experts. In particular, the divergence of science experts centred upon the method for analysing dietary fibre. As noted previously, Southgate (1995) identifies the formation of two main groups: those developing total dietary fibre (TDF) methods and those developing non-starch polysaccharide (NSP) methods. He suggests that the TDF methods emerged from pressure on the US FDA to provide a regulatory framework for dietary claims on food products, while the NSP methods emerged from concern to develop nutritional data bases and to improve understanding of the physiology of the gastrointestinal tract (Southgate, 1995). In short, the groups of scientific experts who were developing methods for measuring dietary fibre were oriented around different premises.

The group of Englyst, Cummings and co-workers were primarily responsible for the development of NSP methods, and the NSP method is often termed the Englyst method. In 1982 Englyst *et al* published a method for determining NSP using gas-liquid chromatography (Englyst *et al*, 1982). Gas-liquid chromatography allows the identification of the constituent sugars of NSP, after starch has been removed. Their procedure involved the measurement of NSP and the separate measurement of starches resistant to digestion (termed resistant starches). According to the authors:

As the measurement of NSP depends on the identification of component sugars after hydrolysis, starch must be removed completely so that any glucose present can be considered as deriving from NSP. In foods such as potato and white flour, there is often 50 times more glucose present as starch than as NSP. Hence a small amount of residual starch can give major errors in NSP glucose determination.

(Englyst *et al*, 1982: 312)

The method proposed by Englyst *et al* (1982) was devised for the identification and measurement of NSP. According to Southgate (1995), the NSP (or Englyst) method first devised in 1982 has been updated and developed since. During the 1980s these developments included improved techniques for separating starch for analysis and simplifying the technical procedures. The pressure to simplify the procedure came as a result of collaborative trials, which suggested that the NSP method suffered from unsatisfactory levels of reproducibility by those analysts new to the technique. However, by 1987 the NSP method could be performed using gas-liquid chromatography and colorimetry, though the latter returned higher values than the former (Englyst *et al*, 1987). Further, collaborative trials were said to confirm the improved precision of the NSP method, and the version employing gas-liquid chromatography became the recommended method of analysis for fibre in the UK (Southgate, 1995).

During the 1980s the NSP method became a recognised method for the analysis of dietary fibre in the UK. Food companies such as Kellogg's, Rank Hovis and Unilever were eager to make claims for dietary fibre content in their food products, in particular cereal products, and the NSP method gave a measure of dietary fibre based upon the non-starch polysaccharides found in the plant cell wall. However, the development of the NSP method was occurring in parallel to the development of total dietary fibre methods (TDF). TDF methods were supported by the Association of Analytical Communities (AOAC). The TDF methods included a broader range of compounds in the definition of dietary fibre. As a result, the application of TDF method for analysis produced higher measures of dietary fibre in food products. The TDF method emerged from work between scientists who had previously been developing independent, though overlapping, methods for analysing dietary fibre. For instance, the method of Asp and co-workers engaged with the work of Schweizer and Prosky. In 1984 a method for analysing TDF was proposed by Prosky *et al*. Where the NSP method uses gas-liquid



chromatography, the TDF method favoured by Prosky and co-workers uses gravimetry. At it most basic, gravimetry involves the production of a precipitate and the weighing of samples. According to Southgate (1995), a gravimetric approach was chosen due to the ease by which analysis can be conducted and the ready availability of the required equipment.

In a review by Asp (1987) – a member of the TDF group – the methods of analysis for dietary fibre are categorised as gravimetric (the TDF method) or gas-liquid chromatographic (the NSP method).<sup>33</sup> Asp (1987) therefore classifies the methods on the basis of the analytical instruments used. He suggests that problems exist with the NSP method as defining dietary fibre as NSP is difficult. To emphasise the problems of demarcating dietary fibre Asp uses the following figure:

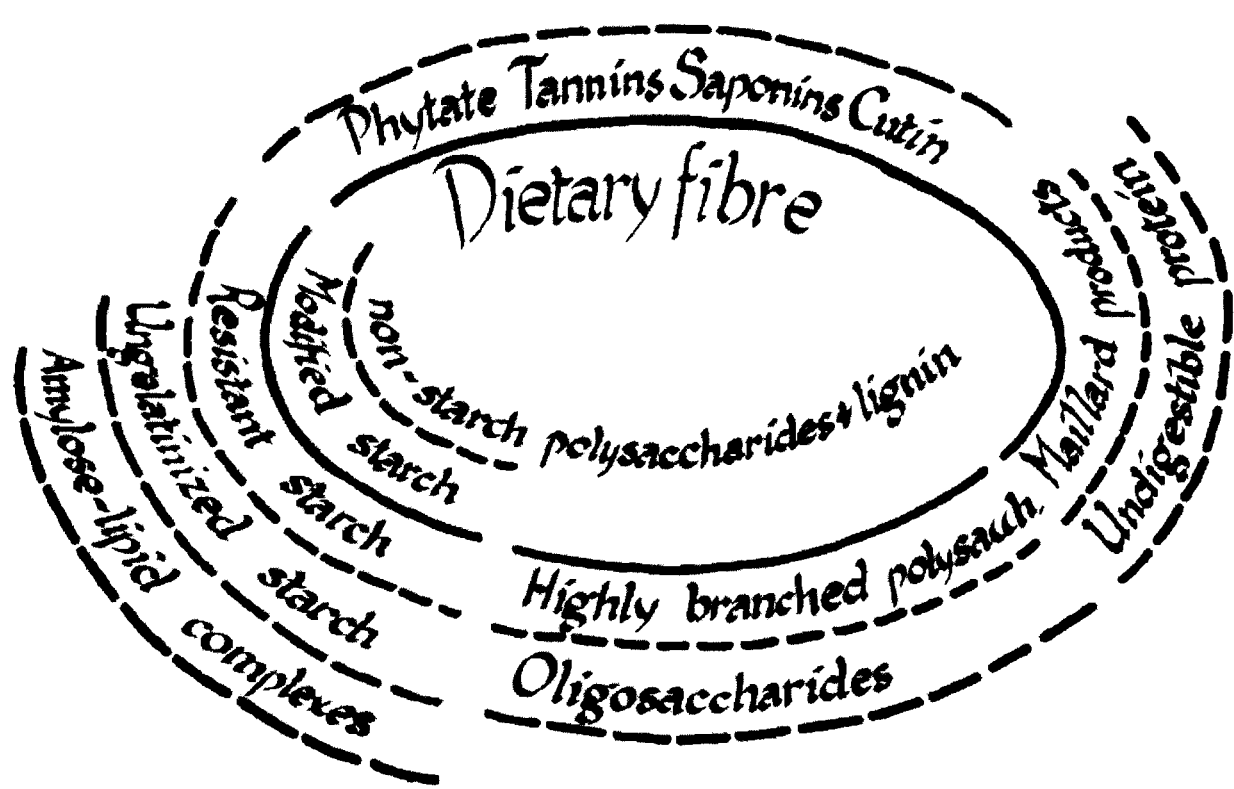


Figure 5.3: The demarcation of the dietary fibre concept (Asp, 1987: 19)

The figure suggests that dietary fibre is a loose collection of carbohydrate compounds. Moreover, the title of the figure is “The demarcation of the dietary fibre concept” (Asp, 1987: 19), emphasising the conceptual understanding of dietary fibre rather than the application of strict chemical definitions.

<sup>33</sup> Colorimetric analysis is mentioned as a third category.

From the 1990s onwards, scientific contention over dietary fibre grew. In 1991 International Life Science Institute (ILSI) Europe convened a workshop in Brussels on the subject of dietary fibre. The workshop led to the publication of an edited volume, containing chapters and records of discussions held at the meeting (Schweizer and Edwards, 1992). In the concluding discussion, Ken Heaton and John Cummings, scientists from the original Burkitt and Trowell grouping and members of the NSP methodology grouping, suggested that the reason dietary fibre is problematic to define and measure is that it is a concept rather than a substance. John Cummings suggested that:

The nearest thing in words we can come to is, I think, that dietary fibre is plant cell wall material. This encompasses a sort of physical and chemical concept without leading one into too many difficulties in terms of physiology.

(Cummings quoted in Schweizer and Edwards, 1992: 340)

For Cummings and Heaton, dietary fibre, as a term developed by Burkitt, Trowell and colleagues, was concerned with the “cellular integrity of food” (Heaton quoted in Schweizer and Edwards, 1992: 338). This definition of dietary fibre was founded upon physical and chemical properties, not with the physiological effects of substances that may or may not be considered as dietary fibre. In response, Thomas Schweizer – a member of the TDF grouping – suggested that indigestibility in the small intestine, a physiological factor, had always been an element of the definition of dietary fibre (Schweizer quoted in Schweizer and Edwards, 1992). Schweizer was emphasising the importance of non-digestibility as a defining characteristic of what could be considered as dietary fibre.

The contention between the TDF method and NSP method gave impetus to the conduct of comparative trials between the two. In a comparison of the NSP method and the TDF method commissioned by the UK Ministry of Agriculture, Fisheries and Food (MAFF), Englyst *et al* (1995) suggest that resistant starch escapes digestion in the small intestine and is present in three different forms: RS1, RS2 and RS3. RS1 includes physically inaccessible starch such as partly milled grain and seed, RS2 comprises resistant starch granules as found in raw potato and green bananas, while RS3 is described as retrograded starch produced by food processing and it said to be present in

cornflakes, bread and cooked potato. The NSP method treats resistant starch as a distinct substance. Englyst *et al* (1995) assert that much of the RS3 present in foods is included in the TDF method, while the Englyst method does not include RS3 as it measures NSP separately from resistant starch. The inclusion of resistant starch, specifically RS3 produced as a result of processing techniques, would become a main area of contention in the definition of dietary fibre.

The Englyst method, if it is to be considered a useful technique for measuring dietary fibre, relies on a definition of dietary fibre which is restricted to non-starch polysaccharides. If dietary fibre is defined as including a range of other substances, such as RS3 or oligosaccharides (short chain polysaccharides), then the claims of those scientists favouring the Englyst method, as an accurate measure of dietary fibre, lose their potency. The precision of the Englyst method in focusing upon NSP has been explicitly criticised in the current draft Codex definition of dietary fibre. It is stated that:

The Englyst method, which is not used world-wide, is complicated and may therefore be less suitable for routine analysis. However, this or similar methods may be necessary in some foods difficult to analyse with the routine methods, e.g. infant formula.

(Codex, 2007a)

Thus the Englyst method is criticised as being too complicated and time consuming for routine analysis. A proponent of the Englyst method, Klaus Englyst, suggests that in fact the opposite is true; that the Englyst method is more straightforward than methods using gravimetric techniques (Interview, July 2008). He suggests that the amount of samples which can be analysed in one run is small for gravimetric methods and that process is labour intensive, taking up to two days.

## 5.4 Disputing Dietary Fibre

During the mid 1990s the lack of scientific consensus over the appropriate definition of dietary fibre and associated method of analysis entered into the international regulatory sphere. As detailed in Chapter Four, dietary fibre became a topic of international

regulatory contention in mid 1990s through discussion in the Nutrition Committee of the Codex. However, the European Commission had instigated meetings in Lyon and Cambridge as early as 1977, in order to develop a consensus over dietary fibre. In the UK, the NSP method was accepted as the recommended measure of dietary fibre in food commodities and products in the mid 1980s. The use of the NSP method meant that the term 'dietary fibre' was not used as a nutritional category in UK dietary reference values, which are used to formulate recommended dietary intakes. Instead of dietary fibre, the term 'non-starch polysaccharides' was deployed (Department of Health (DoH), 1991). In the Report of the Panel on Dietary Reference Values, it was determined that the intake of dietary fibre as NSP in adult diets should be at a minimum of 12g/day, an average of 18g/day and a maximum of 24g/day. However, it is stated that: "In considering the nutritional role of what is known as 'dietary fibre' the Panel was hindered in making a sound scientific assessment of the literature because of imprecision in its terminology." (DoH, 1991: 61). The report goes on to suggest that evidence relating to non-starch polysaccharides would be used instead. Indeed, the title of the chapter is 'Non-starch polysaccharides', giving the term equal status alongside energy, fat, sugars, starches and protein. In the sub-section 'Definition and Analysis', NSP is considered a more precise term owing to the assertion that NSP are "the major component of the plant cell wall and the best single index of the 'dietary fibre' concept" (DoH, 1991: 61). The requirement for precision arises from experimental findings that high levels of certain starches escape digestion in the small bowel and could, if non-digestibility were the basis for definition, be considered as dietary fibre. In essence, the use of NSP in preference to dietary fibre is driven by the policy of excluding resistant starches from a definition of dietary fibre. The definition of dietary fibre pursued in DoH (1991) is strongly linked to the method of analysis for dietary fibre. Having defined NSP as the nutrient category to be defined and analysed, the justification for a method of analysis becomes more straightforward. Enzymatic chemical methods, using gas-liquid chromatography, are considered to be most suitable as they identify NSP specifically. The NSP (or Englyst) technique is described as fulfilling the requirements for a method of analysis.

The definition of dietary fibre favoured by the UK in 1991 excluded many of the components identified by Asp (1987) in figure 5.3. However, at the same time there was an increase in activity by food companies and food scientists and technologists to

produce fibre-enriched or fibre-fortified products, utilising many food components not classified as NSP. In a conference organised by the Royal Society of Chemistry in 1990, Asp (1990: 327) presented a paper addressing the question “to what extent physiological properties of foods naturally rich in fibre can be restored by addition of fibre concentrates or isolates?” and cited the example of Fibrex® (sugar beet fibre) produced by Danisco. New innovations in food science and technology such as Fibrex® continued throughout the 1990s. For instance, the Matsutani Chemical Industry Co Limited began to produce an ingredient which is sold under the trade name Fibersol®-2. Fibersol®-2 is described as a soluble dietary fibre. The suggestion is that Fibersol®-2 can be added to food products in order to increase the amount of dietary fibre present in the product. Fibersol®-2 is a resistant maltodextrin, a type of polysaccharide resistant to digestion. Resistant maltodextrin is produced by hydrolysing starch (from corn, potato and rice) and the process of heating, refining and hydrolysis gives it the properties of indigestibility. Resistant maltodextrins are used in food products as thickening agents, flavour carriers, spray-drying agents, food coatings and fat replacers. Writing from their positions as scientists in the research laboratory of Matsutani Chemical Industry Co Limited, Okuma and Kishimoto (2004: 220) suggest that resistant maltodextrin “...is considered a source, or a component, of indigestible matter commonly known as total dietary fibre.” More recently, National Starch Food Innovation (formerly National Starch and Chemical until a take-over by AkzoNobel) gained approval in January 2008 from the UK’s Advisory Committee on Novel Foods and Processes (ACNFP) to sell RS-4 fibre (Phosphated Di-starch Phosphate) as a food processing ingredient. RS-4 fibre is derived from high amylose maize starch. The appeal of RS4-fibre is to increase the fibre content of foods such as biscuits, crackers, cakes, pastas, pizza doughs, breakfast cereals, tortillas, white flour bread products and pretzels. RS-4 fibre is already used as a food additive (E1413), but the novelty of the application was in its use for nutritional purposes; to raise dietary fibre levels in foods.

The scientific and technological activity focused on the production of fibre fortified products has been described as “dietary fibre technology” (McCleary and Prosky, 2000). As a term, dietary fibre technology captures the notion that dietary fibre is not necessarily something which only exists intrinsically in plants, but is also something which can be manufactured. Writing from this perspective, Alldrick (2001: 243) suggests that:

The chemical diversity of dietary fibre (ranging from plant-derived oligo- and polysaccharides through to microbial exudates and to amylase-resistant starch) and their consequent different physical-chemical properties has led to new dietary fibre-enriched products being marketed. Some of these challenge established perceptions of what is, or is not considered to be, a good source of dietary fibre.

Accepting the chemical diversity of dietary fibre is important to the development of dietary fibre technologies, as a restrictive definition of what can be considered as dietary fibre limits the scope for product innovation. A chemical definition of dietary fibre becomes more difficult the greater the diversity of compounds included.

In considering the variety of components considered as dietary fibre from the technological perspective, one of the architects of the Total Dietary Fibre (TDF) method asks “what is fibre?” (Prosky, 1999; 2001). Prosky suggests that fibre is defined from physiological properties, specifically its indigestibility in the small intestine. From here he quickly moves onto appropriate methods for measuring dietary fibre based upon such physiological properties. Prosky describes the development of a “gold-standard method”: AOAC Official Method 985.29 Total Dietary Fibre in Foods – Enzymatic-Gravimetric Method. This is the method briefly described in Section 5.3 as the TDF method. According to Prosky (2001: 66), because of the outcome of a survey and workshop held in 1981 “and because of its worldwide acceptance, the analytical method for dietary fibre [the TDF method] became the de facto operating definition of dietary fibre.”

Commenting on this, Marcel Roberfroid suggests that:

there has been an evaluation amongst the scientific community, I don't remember when, I think it was in the 80s by Susan Cho in the States who sent a questionnaire to hundreds of scientists in the world, the majority were not in favour of John Cumming's position.

(Interview, April 2008)

Prosky (1999; 2001) claims that a worldwide consensus exists over the definition of dietary fibre as a result of consensus over the appropriate method of analysis. However, this claim is problematic to assert. As Lunn and Buttriss (2007) suggest, disagreement

permeates discussion of which plant-derived compounds constitute dietary fibre and the methodologies that should be used for measurement. They note that a growing number of foods contain carbohydrate-derived ingredients that resist digestion, ingredients that do not fall under the definitions of dietary fibre based on plant-cell wall integrity. For example, non-digestible oligosaccharides, which are carbohydrates with between three and ten monosaccharide units, can be regarded as dietary fibre. Oligosaccharides are an intermediate carbohydrate, having shorter chains than polysaccharides but longer chains than mono- or di- saccharides (see 5.1 Introduction). The potential benefits of prebiotic oligosaccharides to the function of the bowel are recognised, but its categorisation as dietary fibre is contentious.

Broadening the definition of dietary fibre to include compounds such as resistant starch and oligosaccharides has been met with opposition by some. In a letter to the *Lancet*, Goodlad and Englyst (2001: 1833) suggest that:

Defining fibre as non-digestible carbohydrates is very worrying, because it diverts attention from the original concept that it is diets that are rich in unrefined plant foods that are beneficial to health.

For Goodlad and Englyst, non-digestibility is not a strong basis upon which to define dietary fibre. Cummings, a member of the NSP grouping with Englyst, has, with colleagues, considered the merits of the fibre concept in light of these new developments (Cummings *et al*, 2004). They suggest that rather than considering NSP, resistant starch and oligosaccharides as a single macro nutrient, they should be differentiated. In a discussion from the workshop at which this paper was presented, Cummings suggests that oligosaccharides are a totally different group of carbohydrates to NSP, though they may have important properties for maintaining gut health. Oligosaccharides are often termed prebiotics when used in food products and are associated with the stimulation of ‘good bacteria’ in the intestine. An example is the product Beneo™ Inulin produced by the Orafti Group through the extraction of inulin from chicory root. Inulin is an oligofructan, a type of oligosaccharide. Orafti suggest that their Beneo ingredients are more than a soluble dietary fibre due to their partial fermentation by the large intestine. Their assertion is that Beneo products stimulate the growth of *Bifidus* bacteria, a good bacteria. In terms of dietary fibre, scientists from Beneo-Orafti suggest that “Inulin and oligofructose comply with most definitions of

dietary fibres, and they are labelled as such in almost all countries worldwide.” (Alexiou and Franck, 2008: 228). The negotiation of a definition for dietary fibre in Codex responds to such developments. As a result, innovations in the food sector pose challenges for international standard-setting.

## 5.5 Conclusions

The aim of this Chapter was to detail the history of scientific dispute over the definition of dietary fibre and the methods for its analysis. Three phases in the development of the definition were identified. The section ‘Discovering Dietary Fibre’ detailed the first coherent use of the concept of dietary fibre by Trowell and Burkitt. As a result of their work, growing activity began to take place in order to better understand the chemical composition and physiological effects of dietary fibre. The attention to the chemical composition of dietary fibre placed a new emphasis upon devising suitable methods of analysis. By the late 1970s distinct groups of scientists were working on particular methods, with implications for the definition of dietary fibre. The Section ‘Defining Dietary Fibre’ focused upon the development of methods of analysing dietary fibre alongside the growing public awareness of the concept. Thus, while the dietary fibre concept was entering public consciousness, dietary fibre scientists were in disagreement about how to define the concept and how to measure dietary fibre in foods. The lack of consensus over dietary fibre, in the context of new food products and technologies, was detailed in the section ‘Disputing Dietary Fibre’. The emergence of dietary fibre technologies, derived from resistant starches and oligosaccharides, provoke new questions of what constitutes dietary fibre.

The overall intention of Chapters Four and Five was to detail the controversy of defining dietary fibre through the lens of the Codex standard-setting process, in the case of the former, and through the lens of scientific activity and debate, in the case of the latter. A feature of both chapters was the interrelationship between regulatory concerns, commercial opportunities and scientific discussions. Chapter Five, despite being primarily concerned with the development of scientific disagreement over dietary fibre, had to also address developments happening in the regulatory sphere. The recognition by the UK DoH of non-starch polysaccharides, the organisation of workshops by the



European Commission in 1977/78 and the criticism of the NSP (Englyst) method in the draft Codex definition all featured in Chapter Five as part of the narrative of scientific dispute. Likewise, Chapter Four, despite being focused on the standard-setting activities of the Codex Nutrition Committee, had to consider scientific definitions and debates (such as the use of NSP in the FAO/WHO definition and the presentations by scientists at the ILSI side-event). The interrelationship between science and politics is the focus of the following chapter, Chapter Six. The notion of expertise is used as a way of considering how the interrelationship between science and politics is mediated and constituted. Chapter Six brings together the insights of Chapters Four and Five and implements more focused analysis on the role of expertise in the production of the dietary fibre definition.

## **Chapter Six – Knowledge Claims and the Definition of Dietary Fibre**

### **6.1 Introduction**

This Chapter begins by introducing further empirical material on the standard-setting process for dietary fibre. Section 6.2 details how governments, international organisations and industry groups contributed to the standard-setting process through the use of scientific advice. Scientific advice on the definition of dietary fibre has been produced through various channels. Four domains in which knowledge claims over dietary fibre have been produced are explored in greater detail within the section: European Commission, United Kingdom (UK), United States (US) and the FAO/WHO. The section details how regulatory activities in these arenas intersect to produce disagreement amongst interested parties. In particular the lack of a designated risk assessment body to the Codex Nutrition Committee is identified as an institutional factor contributing to the heightened state of contention.

Section 6.3 is concerned with the formation of knowledge claims as scientific advice. The role of measurement and the methods used for measurement is identified as a crucial element of contention. Taking cues from work within science and technology studies (STS) on the sociology of scientific knowledge, the section explores how measurement can become a topic of conflict, with the effect of encouraging further disagreement over the definition of dietary fibre.

### **6.2 Scientific Advice and the Definition of Dietary Fibre**

In this section, the sources of scientific advice which informed the eventual consensus on dietary fibre will be discussed. In particular, activity in four arenas will be discussed: the European Commission, UK, US and FAO/WHO. The role of the European Commission is of particular significant to the standard-setting process for dietary fibre. The European Commission, supported by scientific advice from the European Food Safety Authority (EFSA) was highly active in producing the draft

Codex definition on dietary fibre, as agreed in the Codex Nutrition Committee in November 2008 and adopted by the Codex Commission in July 2009. Moreover, the European Commission Directive defining dietary fibre was agreed in advance of the Codex definition, thus exerting considerable pressure on discussions in the Codex. The case of the UK is of particular interest in this context. The UK was the only EU member state which expressed disagreement with the draft Codex definition (and by implication the EU definition) and was the home nation of many of the dietary fibre scientists who coalesced around the early work of Hugh Trowell and Denis Burkitt (as discussed in Chapter Five). In the US, the on-going conduct of regulatory science for the purposes of setting regulations covering dietary intakes meant that a fixed position could not be adopted within Codex negotiations. Finally, the scientific advice produced by the FAO/WHO proved to be crucial to the active discussion of scientific advice amongst Codex member governments and industry groups.

Before examining these four domains of scientific advice and regulatory activity, it is worth reviewing that the dispute over the dietary fibre definition in Codex did not prevent an agreement being reached. As demonstrated in Chapter Four, agreeing a definition for dietary fibre proved difficult in the Codex. Work on this issue was undertaken in 1992, but substantive debate did not begin until 2000, as the question of how to define and measure dietary fibre was frequently avoided and discussion moved to future meetings. Despite the initiation of discussion in 2000 and the steady refinement of a draft definition, by 2007 member governments could still not agree on a conclusive outcome. In this respect, the FAO/WHO Scientific Update had a significant impact. The Scientific Update offered a definition which directly contradicted the working draft Codex definition and so the standard-setting process was significantly influenced by the production and articulation of scientific advice by the FAO/WHO. Member governments suggested they needed more time to review the Scientific Update and the 2007 meeting closed with dietary fibre still an unresolved agenda item. When the Nutrition Committee reconvened in November 2008, a draft definition and table of values for dietary fibre was agreed. The agreed definition was adopted at the July 2009 meeting of the Codex Commission, a significant development in the longstanding disagreement over dietary fibre.

The adopted definition represents a compromise solution in three main ways. Firstly, national governments are free to determine whether to include shorter chain polysaccharides (such as oligosaccharides) as dietary fibre. Secondly, the definition allows for the inclusion of synthetic and recovered carbohydrate polymers as dietary fibre, so long as these components can be demonstrated to have a physiological effect or benefit to health. Thirdly, national governments are free to determine the required nutrient content level for claims ('source of' or 'high in') made for dietary fibre in liquid foods. However, the question of the most appropriate methods of analysis for measuring these components has been left for further discussion. Therefore, the agreement reached in 2008 is, in a number of ways, open to interpretation. As a result, the ability of food companies to make claims on the dietary fibre content of food will continue to vary between countries. Under the new definition, national governments are deemed able to make decisions over whether to classify oligosaccharides as dietary fibre, as no international agreement could be established on the minimum length of the carbohydrate polymers. The draft definition as it stood in 2007 suggested that any carbohydrate polymers with three or more monomeric units could be classified as dietary fibre. However, in 2008 the emphasis had changed, with the definition now stating that ten or more units was acceptable as dietary fibre, while judgements on three to nine units would be left to national governments. Therefore the nutrient content claims for dietary fibre on food products will vary depending upon the approach taken by national governments.

#### 6.2.1 European Commission and Scientific Advice

The ability for national governments to interpret aspects of the definition as they see fit means that the problem of agreeing an international definition, in a context of conflicting national regulations, has been avoided. In particular, this has avoided conflict with the EU definition agreed in October 2008. The agreement of an EU definition of dietary fibre had a significant impact upon the negotiation of the Codex definition and the European Commission has had a major influence upon the Codex standard-setting process for defining dietary fibre.

The influence of the European Commission has become more apparent since 2003 with formal recognition in the Codex. Prior to 2003, EU member states were active on all

standards discussed in the Codex, even if a corresponding EU Directive or Rule existed. A significant change occurred in 2003 when the European Commission (termed European Community in Codex) became recognised as a member organisation of Codex, giving it the same powers as Codex member government delegations. In order for this to happen a protracted debate took place in the Codex Committee on General Principles, as the rules governing procedures in the Codex were revised (Poli, 2004). In matters covered by EU law, the European Commission was granted competency to represent the EU member states in the Codex. Therefore, when the subject matter of Codex standards correspond to an existing EU law, the European Commission speaks on behalf of member states. As a result, the European Commission makes frequent interventions during the sessions of Codex committees. This means that the European Commission – in staffing the EU representation to the Codex - occupies a central role in the negotiation of Codex standards. Further, the role of EFSA, as the primary source of scientific advice to the European Commission, is enhanced relative to the national advisory committees of EU member states.

Before the European Commission became a recognised member organisation of Codex, EU member states co-ordinated around issues where there was EU legislation. However, the recognition of the European Commission as a member organisation in Codex means that EU member states have a formally co-ordinated response to matters covered by European Commission competency. With the recognition of the European Commission as a Codex member organisation, the co-ordination meetings of EU member states became focused upon the agreement of a position to be presented (and negotiated) by the European Commission in Codex standards covered by such competency. The delegation of authority in EU co-ordination meetings therefore turns upon the question of competency. If the European Commission has competency over an issue to be discussed in Codex, EU member states will need to agree to a co-ordinated position which the European Commission will represent. In the case of dietary fibre in the Codex, competency between the European Commission and EU member states was mixed, although the European Commission had exclusive right to vote if necessary. Mixed competency occurs when a Codex standard involves some discussion of topics covered by EU legislation and others covered by the domestic rules of EU member states. At that time the European Commission had a directive, the Nutrition Labelling Directive (Directive 90/496/EEC), which would cover dietary fibre

once an agreement between the European Commission and EU member states had been reached. In the situation of mixed competency, the European Commission takes the lead, while EU member states are free to make interventions if they wish (Alemanno, 2007). By holding the right to vote on dietary fibre the European Commission has the privilege of voting on behalf of EU member states and is the ultimate decision-maker. Speaking before the eventual agreement of the Codex definition, one government delegate explained the European Commission situation as:

among the member states, until December last year [2007], the situation was very simple, it was not a harmonised area. So each member state probably had some definition of dietary fibre. But the common understanding was that we were discussing a definition of dietary fibre at Codex level, and once this definition has been agreed by Codex it would be taken up as an EC definition. So the EU countries have an open mind on the definition of dietary fibre. Since 2007 there was a new regulation dealing with nutrition in the EU so it became a harmonised area, shortly after the last [Codex] nutrition committee. The regulation was published shortly after the nutrition committee but it was agreed by the Ministers and Parliament a bit before. So everybody has accepted that it was a harmonised area but it was still to be defined in the EU. So we were still on the old policy of waiting for Codex to provide some sort of definition and taking it up. Of course it did not happen last year, so we wait and see what we do in November 2008.

(Interview, May 2008)

The enhanced status of the European Commission within Codex, giving it privileges over EU member states in areas of competency, means that the ability of member states to intervene in Codex has been reduced. As a result of the restriction placed upon EU member states intervening during the conduct of Codex meetings, more emphasis is placed upon pre-Codex co-ordination meetings in Brussels.

According to one government delegate:

the European Commission co-ordination meetings are really important, that's where you, as a member state, get your input, that's the stage where you put all your energies and the preparation goes in...to come to positions that are then brought here [the Codex].

(Interview, November 2007)

Co-ordination between EU member states is informed by national sources of scientific evidence, demands made by domestic food industries and, importantly, by the scientific evidence produced by EFSA. The scientific advice offered by EFSA is central to the positions proposed by the European Commission during co-ordination meetings. According to one official, EFSA advice is seen as a point of departure for discussions which take place between the European Commission and EU member states (Interview, April, 2008). The same official suggests that a sense of mutual understanding exists between EU member states over EFSA advice, though admittedly “Sometimes it is a question of how you translate EFSA opinion into legislation.”

As suggested above, the European Commission position was supported by EFSA advice (EFSA, 2007c). The advice was published in July 2007 in response to a request by the European Commission and its publication was timed in advance of the discussions detailed in Chapter Four. The EFSA advice sought to clarify the European Commission position on dietary fibre in order to produce a recommendation for European Commission legislation and which would also provide a basis for negotiations in the Codex Nutrition Committee. EFSA produced a brief conclusion, that dietary fibre should include all non-digestible carbohydrates plus lignin (EFSA, 2007c). Such a definition includes non-starch polysaccharides, resistant oligosaccharides and resistant starch. It is therefore a significantly broader definition of dietary fibre than that proposed by the FAO/WHO in the Scientific Update. The advice of EFSA on dietary fibre, timed in advance of the 2007 meeting of the Codex Nutrition Committee, has the effect of binding EU member states to this scientific opinion, given that the European Commission has competency on the dietary fibre issue. However, the production of the EU Nutrition Labelling Directive had an impact beyond the EU member states. The European Commission agreed on amendment to the directive which defined dietary fibre. This was done a matter of days before the Codex Nutrition Committee was due to meet in South Africa. The amending directive to the Nutrition Labelling Directive gave a definition of dietary fibre directly corresponding to the recommendation made by EFSA. Therefore, in 2008 negotiations within the Codex over dietary fibre had to be conducted in the context of agreed EU legislation on the topic.

The amending directive which defined dietary fibre in Europe emerged through the comitology procedure of the EU, a system of rule-making via committees and

augmented by working groups involving experts on the topic under discussion. Joerges and Neyer (1997) have described the comitology procedure as fostering a process of co-operation and mutual understanding between the European Commission and EU member states, rather than implementing a hierarchical system of policy-making. For the amending directive on dietary fibre, the first deliberations on the proposal put forward by the European Commission occurred in the working groups between experts representing the EU member states. Then procedures were initiated within the European Commission to ensure agreement on the amending directive, which then passed to the Standing Committee on the Food Chain and Animal Health, Section on General Food Law, in order for votes to be cast. At this point the amending directive had moved from expert working groups to a regulatory committee. The relevant committee met on 23<sup>rd</sup> June 2008 and discussed and voted on the amending directive, amongst other items. It was noted that only one member state disagreed with the text presented (CEC, 2008c).

As suggested above, on 29<sup>th</sup> October 2008, days before the meeting of the Codex Nutrition Committee, the European Commission published the amending directive. Thus, the new EU definition of dietary fibre is:

...carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories: edible carbohydrate polymers occurring in food as consumed; edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence; edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence.

(CEC, 2008b)

The first element of the definition, which concerns monomeric units, addresses the oligosaccharides question. So long as there is “a beneficial physiological effect demonstrated by generally accepted scientific evidence”, oligosaccharides can be included as dietary fibre. Non-digestibility is the critical characteristic of dietary fibre in the EU definition. If a carbohydrate polymer meets the conditions of non-digestibility and requisite number of monomeric units, it can be considered as dietary fibre under three categories. These categories are broad and include carbohydrate



polymers extracted from food raw material and those created synthetically. The agreed Codex definition of dietary fibre is similar to the EU definition. It retains the three-fold category of intact, recovered and synthesised carbohydrate polymers, with the need for physiological evidence for the latter two. Similarly, the concept of non-digestibility is retained. On the question of oligosaccharides, the Codex definition avoids making an international agreement and instead it is said that the “Decision on whether to include carbohydrate from 3 to 9 monomeric units should be left to national authorities.” (Codex, 2008d).

The impact of the European Commission upon the eventual Codex definition of dietary fibre is significant. Debate over the definition of dietary fibre took place in the EU for a number of years prior to discussions in the Codex. In particular, European activity over dietary fibre science gathered momentum during the 1990s. In the early 1990s, the European Concerted Action for Cooperation on Science and Technology (COST 92) undertook work on dietary fibre, while the EU Scientific Committee on Foods (SCF, now superseded by EFSA) also sought to arrive at an agreed definition. No consensus could be reached. A meeting did take place between various dietary fibre scientists in Paris, which also involved members of SCF. According to Marcel Roberfroid, the meeting was productive and he left with the impression that a possible agreement had been reached (Interview, April 2008). However, UK scientists such as John Cummings and Philip James<sup>34</sup> remained opposed to a definition of dietary fibre beyond those polysaccharides found within the plant cell wall. Further European research activity on dietary fibre was stimulated by the launch in 1995 of the Coordinated EC Concerted Action on Functional Food Science in Europe (FUFOSE), managed by ILSI Europe. ILSI continued to have an influence upon dietary fibre science in Europe, as will be discussed in Section 6.2.4. Yet, despite scientific activity across Europe on dietary fibre and a series of meetings aimed at brokering an agreement, no consensus could be reached. The co-ordination between EU member states over dietary fibre was not completely harmonious, due primarily to the position of the UK. Prominent UK scientists such as Cummings and James were opposed to the definition proposed by the European Commission and other EU member states. The UK government position

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<sup>34</sup> James was responsible for drafting a report which set out the blueprint for the UK Food Standards Agency (see James, 1997).

sought to resist a broad definition of dietary fibre, as favoured by the majority of other EU member states and by the European Commission.

### 6.2.2 United Kingdom and Scientific Advice

By departing from the proposed EU definition, the UK remained unconvinced by the scientific advice being offered by EFSA. The policy position of the UK on dietary fibre remained based upon non-starch polysaccharides found in the plant-cell wall (DoH, 1991). Such a position was in keeping with the arguments made by Cummings and James against the EU definition. During 2007, as momentum built within the EU to agree a definition, the UK responded by seeking to produce a definitive statement on dietary fibre. The UK FSA instigated a number of activities, including conducting a consultation on the amendment to the EU directive and issuing a call for evidence on the potential health benefits of dietary fibre. Conducting a consultation on a new aspect of EU legislation was a procedural activity; interested parties within the UK would expect to be able to submit comments on such a change, as detailed in the Statement of General Objectives and Practices of the FSA (FSA, 2000). The consultation provoked responses by a number of interested parties. As dietary fibre scientists, Klaus Englyst and Hans Englyst detailed their concerns over the proposed EU definition of dietary fibre in a written response to the consultation:

it is our opinion that the definition proposed in the amending directive is inappropriate because it has the potential to both mislead consumers and would add further confusion rather than clarification to the legal requirements for industry and enforcement authorities. Instead, we suggest a more appropriate definition would be 'intrinsic plant cell wall polysaccharides' as endorsed by the recent FAO/WHO scientific update on carbohydrates in human nutrition. This definition forms part of a structured approach for describing and measuring all food carbohydrates. Such a system would include scope for the separate labelling and claims for other types of carbohydrate with specific functional properties, without jeopardizing the existing public health messages that have established dietary fibre as integral with a plant rich diet.

(Englyst and Englyst, 2008)

In this response by Englyst and Englyst (2008) it is possible to see how different sources of scientific advice interact. Firstly, as dietary fibre scientists, Englyst and Englyst can offer scientific opinion on the relative merits of different definitions.

Secondly, they draw upon an international source of evidence, the FAO/WHO, in contributing to the discussion taking place to formulate scientific advice within the UK. Thirdly, the formulation of this advice is happening in response to activity within the EU on the definition of dietary fibre. A group of food companies and industry bodies (including Nestle, Tate and Lyle, Danisco, GlaxoSmithKline, Food and Drink Federation, and the Food Additives and Ingredients Association) also responded to the consultation and in doing so drew upon international sources of scientific advice. These groups stated their agreement with the proposed EU definition and cited the scientific advice of EFSA in support of this. They also noted how the proposed EU directive was in line with the draft Codex definition. However for some industry groups the definition did not go far enough. The Provision Trade Federation (PTF), suggested that, in keeping with the advice of the International Dairy Federation (IDF), some indigestible disaccharides ought to be included.

The UK consultation over the proposed EU directive revealed that debates in the Codex were closely linked to debates taking place at the European level. In the consultation comments, the draft Codex definition was cited by some parties as being in line with the proposed EU definition. Others, such as John Cummings, suggested that it was premature to proceed with an EU definition until an agreement had been reached in Codex. As expected, the consultation produced divergent opinions on how the UK should respond to deliberations in the EU and Codex. In order to situate any decision on dietary fibre, a second strand of activity was undertaken by the UK FSA. This involved a call for evidence on the health benefits of dietary fibre components. As noted, the position of the UK over dietary fibre stood in contrast to the opinion of EFSA. Although EFSA did not produce a final statement on the definition until 2008 - a definition which then worked its way through the European Commission comitology process - the UK had already undertaken work to produce scientific evidence to inform a definitive UK statement on the definition of dietary fibre. A call for evidence was issued in December 2007. In the call, it was stated that "The completed review will be considered and discussed by the Scientific Advisory Committee on Nutrition (SACN), who will agree the final draft of the document." (FSA, 2007: 2). As the primary source of advice to the UK government on matters of nutrition, SACN has considerable influence on the way that scientific evidence is configured. The work of SACN, as a scientific advisory committee, is carried out in the form of open, general meetings and through closed working groups which deal with specific topics. In April 2008, around

the same time the consultation on the amendment to the Nutrition Labelling Directive was completed, SACN convened a working group on the topic of carbohydrates. As detailed in the minutes, this first meeting was primarily concerned with the work being undertaken to define dietary fibre. In particular, members of SACN discussed the narrative review being carried by Alison Stephen (a contributing scientist to the FAO/WHO Scientific Update) and Louise Aston, of Human Nutrition Research (Cambridge), who were the successful applicants in the call for evidence. It was suggested that main driver for the work being undertaken by Stephen and Aston was to strengthen the UK position in the on-going debates in Codex. The UK government was therefore supporting a scientific review in response to activity in the Codex (and by implication the European Commission). During this first meeting, discussion took place about the variations between conceptions of dietary fibre in the EU, UK and US. A member of the working group suggested that problems would arise if SACN agreed a definition for dietary fibre which was different to that agreed by Codex and/or the EU.

In June 2008 SACN produced a draft position statement which sought to clarify the UK position on dietary fibre. Based on the evidence presented, SACN concluded that non-starch polysaccharides and soluble fibres (from oats, psyllium, pectin and guar gum) were the only groups which could be considered to be components of dietary fibre. For any other group to be considered as dietary fibre, the proposed physiological effects would need to be demonstrated. The position statement included little reference to analytical methods, except where a particular method had been used by a study. Instead it considered the outcomes of intervention and observational studies dealing with the effects of potential dietary fibre components upon: obesity, cardiovascular disease, colorectal cancer, colonic function and prebiotics. The new UK definition for dietary fibre set out by SACN marked a departure from the previous definition which was based upon non-starch polysaccharides as identified by the Englyst method. Now, other components could be considered as dietary fibre if a proposed physiological effect could be demonstrated. The definition of dietary fibre would therefore become dependant upon the assessment of the physiological effects exhibited by components such as resistant starch and oligosaccharides.

In the UK, the definition of dietary fibre changed during 2008. The concise definition based upon non-starch polysaccharides found within the plant-cell wall (DoH, 1991)

had been replaced by a slightly broader definition which required evidence of beneficial physiological effects (SACN, 2008). However, despite this movement, representatives from the Beneo-Group and National Starch Food Innovation were reported in the trade publication Food Manufacture as being unhappy with the draft definition proposed by SACN, suggesting that it placed unnecessary restrictions upon what could be included as dietary fibre (Twinn and Watson, 2008). Despite the continued disagreement between interested parties, the issues raised by the SACN draft definition on dietary fibre were, in some ways, largely hypothetical. As a result of the advances in establishing an EU definition, by 31<sup>st</sup> October 2009 all EU member states will have to align with the definition of dietary fibre included in the EU amending directive on nutrition claims. In this respect, the activity undertaken by the UK FSA was too late to impact upon the EU directive, but a decision on dietary fibre from SACN was seen as a necessary undertaking. As the primary source of advice for the UK on nutrition issues is SACN, a SACN statement on dietary fibre was necessary (Interviews with Government Delegate, February and November 2008). Further, early in 2008 the need to produce a SACN response to negotiations in the Codex was seen as important by the UK FSA. As noted by a member of SACN, the scientific review of dietary fibre in the UK was being conducted in relation to developments in Codex (Personal note, February 2008). Codex standards assume a heightened significance to the UK if the standard in question is covered by EU legislation, as in the case of dietary fibre. This is due to the understanding that the European Commission negotiates EU food standards alongside the negotiation of Codex standards (Interview with Government Delegate, February 2008). As a result the UK has to act in both European and International contexts in order to input into the standard-setting process.

### 6.2.3 United States and Scientific Advice

While the European Commission was highly active in setting the agenda for defining dietary fibre, the US adopted a more tentative position. As Dratwa (2002) has noted, the Codex is an institution in which the European Commission is an important actor, but the European Commission officials participating in Codex standard-setting pursue policy objectives in negotiation with national governments outside of the EU. Amongst member governments of Codex with which the European Commission must negotiate, the US is particularly significant (Vogel, 1995; Dratwa, 2002; Veggeland and Borgen,

2005). In the case of dietary fibre, the US was one of the first Codex member governments to suggest that it would be able to contribute new scientific evidence to the process at a point when discussion had reached an impasse. As detailed in Chapter Four, the Institute of Medicine of the National Academy of Sciences (IoM) undertook a large study of dietary reference intakes, which included a definition of dietary fibre. However, although the US was heavily involved in the discussions over dietary fibre, the definition agreed in the 2008 meeting of the Codex Nutrition Committee was met with reservation by the US delegation. In the final report of this meeting it was suggested that:

The Delegation of the United States expressed concerns that the proposed definition contained significant modifications to the previous text considered...the United States recommended that the Committee have additional time to reflect on the proposed definition and its implications before the definition is advanced for adoption.

(Codex, 2008d)

Despite the close involvement of the US in discussions over dietary fibre, and their timely production of scientific evidence and advice through the IoM report, the definition agreed in Codex was not met with approval by the US delegation. An important factor in the US adopting this position was the domestic regulatory situation. According to one delegate, the US is still formulating a definition of dietary fibre and so could not take a strong position on the definition in Codex (Personal communication, January 2009). John Cummings also suggests that the US is not necessarily unhappy with the Codex definition, but had to leave options open until domestic regulation has been settled (Interview, December 2009). As a result, the US confined its interventions to highlighting the unresolved issues. For instance, the US delegation raised a number of questions about the definition, including how to define and measure physiological effects and the potential consequences of the Codex definition for public health:

The United States believes that the Committee should consider the following questions: Is there sufficient scientific evidence to indicate that a revised Codex dietary fiber definition is needed to improve public health? Is there international scientific consensus on the term(s) to be defined (e.g. “dietary fibre”, “fibre”, “total fibre”, “synthetic/isolated fibre”, “(beneficial) physiological effect” and on the definition(s)? Is there a validated method or validated procedure for

combining methods to measure total fibre content based on the proposed definitions in various food matrices?

In addition to these concerns, the US delegation set out a further eleven questions to be addressed before a satisfactory agreement could be reached. The questions raised by the US reflected the on-going national regulatory process and drew attention to the inconclusive status of the scientific advice.

#### 6.2.4 FAO/WHO and Scientific Advice

Given the objections of the US to the definition agreed in Codex, it would seem unlikely that the EU, Codex and US definitions of dietary fibre could be regarded as harmonious. However, the definition of dietary fibre agreed in the Codex was viewed by some as being in keeping with the outcomes of the IoM report. In a presentation to an ILSI workshop on dietary fibre held in advance of the 2008 meeting, Joanne Lupton, Professor of Nutrition at Texas A & M University, suggested that the IoM definition of total dietary fibre allowed for the inclusion of oligosaccharides. Lupton regarded this as being in line with both the EU and Codex definitions, but in contradiction to the FAO/WHO definition. Again, on the other contentious topic of whether to include resistant starch in a definition of dietary fibre, Lupton highlighted that the US definition, based on the IoM report, was in line with the EU and Codex. The analysis of Lupton aligned the US position on dietary fibre to that of the EU and Codex, yet the US expressed reservations about the Codex definition agreed in the Nutrition Committee. The US delegation distanced the US position from that agreed in Codex, not by directly challenging the consensus and bring a vote to the committee, but instead by detailing questions it considered unresolved and by expressing a concern that insufficient time was allowed for discussion. In this way the US ensured that the records would show it did not necessarily agree with the Codex definition and so would have scope to debate in the setting of domestic regulation.

As suggested above, ILSI have been actively involved in the debate over dietary fibre. In 2007 I attended an ILSI workshop held in advance of the Nutrition Committee meeting, which comprised a number of presentations by scientists sympathetic to the draft Codex definition as it stood at that time (as detailed in Chapter Four). This meeting also provided ILSI with an opportunity to draw attention to the concise

monograph produced on dietary fibre, which sets out the ILSI position on the issue (see Gray, 2006). Of course, nothing was agreed at the 2007 Codex Nutrition Committee in which the FAO/WHO Scientific Update was presented and ILSI representatives expressed their dismay that discussion would go on for another year. When the Nutrition Committee reconvened in 2008, ILSI again held a workshop covering dietary fibre. However, alongside Joanne Lupton, John Cummings was invited to speak. Cummings presented on the FAO/WHO definition of dietary fibre, the definition considered by Lupton to be at odds to the other main definitions (these being the definitions offered by Codex, European Commission and US). As a result of the presence of Cummings, the ILSI workshop was an event in which conflicting opinions on the definition of dietary fibre were discussed at an early stage. The reasoning for this configuration was not entirely strategic on the part of ILSI. According to Loek Pijls of ILSI, the FAO/WHO agreed that the ILSI workshop could be an official component of the Nutrition Committee – as it was in 2007 – so long as ILSI incorporated John Cummings into the event (Interview, December, 2008). Thus, the ILSI workshop, which in 2007 seemed to involve galvanising opinions in favour of the draft Codex definition, had become an arena in which contention and disagreement could be explored.

ILSI workshops represented an opportunity for food industry groups to present scientific advice as they see it. The role of ILSI as a source of scientific advice takes on a particular prominence in the Codex Nutrition Committee given that this risk management committee does not have a corresponding risk assessment committee. As detailed in Chapter Three, the Codex risk analysis framework involves a division between risk assessment (comprising scientific evidence and advice) and risk management (comprising standard-setting activities). The division within Codex between risk assessment and risk management places pressures upon the FAO/WHO to ensure that scientific advice is available in order for standard-setting activities to be conducted within Codex. If scientific advice is requested by a Codex risk management committee then FAO/WHO should be able to provide this. If a Codex risk management committee has a corresponding expert group, it should at least be clear where the request should be directed to. For those Codex risk management committees without a corresponding expert group, the relationship between the committee and the FAO/WHO, as risk assessors, becomes more uncertain as there is no formal



organisational relationship between these committees and FAO/WHO. Risk management activities conducted in Codex committees should be undertaken on the basis of scientific advice from FAO/WHO. If this advice is not available from FAO/WHO, but advice is still required, then other expert groups may become more influential in the standard-setting process. ILSI is one such organisation. In 2008 it would seem that FAO/WHO acknowledged the role played by ILSI as a ‘broker’ of knowledge between industry and regulators and sought to change the terms upon which ILSI operated in Codex meetings. Rather than ILSI holding an event as a component of the Codex meeting and having scope to devise the workshop, FAO/WHO stipulated that the workshop had to include input from FAO/WHO Scientific Advice. This situation – whereby FAO/WHO felt the need to enforce the discussion of their advice within an industry group event – suggests that scientific advice produced by FAO/WHO suffered from a lack of authority.

The authority of the advice of FAO/WHO on dietary fibre was challenged by food industry groups who were concerned about the ability of food companies to make nutrition and health claims for their products. These groups – such as the European Starch Industry Association (AAF), the International Alliance of Dietary / Food Supplement Associations (IADSA), the International Dairy Federation (IDF), the International Council of Grocery Manufacturers Associations (ICGMA) and the International Special Dietary Foods Industry (ISDI) – sought to input into the standard-setting process. Some of the concerns of these groups were manifest in the ILSI workshops held in 2007 and 2008. Another method used to provide input to the standard-setting process was the submission of comments to the Nutrition Committee. No industry groups expressed unreserved support for the FAO/WHO definition, but some were careful to express agreement with the importance attached to intrinsic plant cell wall polysaccharides. For instance, IDF acknowledged the value of intrinsic plant cell wall polysaccharides, but suggested that the concept of dietary fibre incorporated other components. However, the IDF also suggested that new components, not included in the draft Codex definition, should be included on the basis of “more recent scientific knowledge” (Codex, 2008b). The broadening of the definition beyond the non-starch polysaccharides found in fruits, vegetables and wholegrains (‘intrinsic dietary fibre’ to use the language of the FAO/WHO scientific advice) is seen as important by IDF in order to avoid dietary fibre being ‘undervalued’. Attempts to use such a definition as a

marker for a healthy diet are thus criticised as being too restrictive and ignoring the potential of other components (for example, the various forms of oligosaccharides found in products such as Muller ‘Vitality’ yoghurts). According to IDF, and in contradiction to the FAO/WHO, the primary defining principle of dietary fibre is the indigestibility of dietary fibre in the small intestine. Other facets of dietary fibre should therefore be regarded as secondary to this feature.

That industry groups will challenge regulation which may impede the marketing of their products is not surprising. But in Codex these challenges must take place within a framework of scientific advice to risk managers. However, there is no designated risk assessment committee for the Codex Nutrition Committee. As a result, the FAO/WHO has to assert the primacy of the scientific advice it provides against other sources. The Codex Nutritional Risk Analysis Principles (adopted in July 2009) set out the terms upon which scientific advice to the Nutrition Committee should be conducted:

Consistent with their important role in providing scientific advice to Codex Alimentarius and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex Alimentarius. This acknowledgement however, does not preclude the possible consideration of recommendations arising from internationally recognised expert bodies, as approved by the Commission.

(Codex, 2008)

Therefore, should these principles be adopted, the FAO/WHO will be considered the primary source of advice to the Nutrition Committee. At the 2007 meeting of the Nutrition Committee, the question of scientific advice for nutrition was raised during discussion of these principles. The FAO representative at this meeting emphasised that FAO/WHO Joint Expert Groups give independent advice and should probably be the only source of advice for Codex committees (Personal note, November 2007). The FAO representative took issue with the suggestion that other sources of advice could be chosen by the Nutrition Committee and stated that if a request for scientific advice is made by a Codex committee then the FAO/WHO are obliged to meet this request (Personal note, November 2007). The delegation of Malaysia agreed that the FAO/WHO Joint Expert Groups should be the primary source of scientific advice. In contrast, the delegation of the European Commission asked whether the text of the nutritional risk analysis principles should reflect the need to seek scientific advice from

other sources. The ability of the FAO/WHO to deliver scientific advice is crucial to standard-setting in the Codex if the parent organisations are designated as the primary source of scientific advice. This is problematic. The European Commission takes its scientific advice on food safety and nutrition primarily from the European Food Safety Authority (EFSA), not FAO/WHO Joint Expert Groups. The FAO/WHO can assert its authority in the provision of scientific advice through reference to the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (FAO/WHO, 2007). But this framework is applicable only to the sphere of international standard-setting as conducted in the Codex and sister organisations (World Organisation for Animal Health and the International Plant Protection Convention). Likewise, other member governments of Codex take scientific advice from other national and international scientific expert bodies outside of the UN system. However, the lack of a standing committee for scientific advice on nutrition has not resulted in an absence of scientific input from the FAO/WHO in Codex standard-setting, as evidenced in the case of dietary fibre. Here, FAO/WHO have proactively provided scientific advice which has not been requested by risk managers. According to a delegate to the Nutrition Committee, the case of dietary fibre was a classic situation of scientific advice being produced in a competitive relationship with other sources of advice:

I think there is a real admission from the commission that there are other bodies around that will also produce sound science and have the adequate expertise to provide advice as well, whether it be from different national bodies or whether it be groups like the European Food Safety Authority or there a certainly a range of bodies you'd want to review all the evidence. The classic would be dietary fibre. If we as a committee had the only expert advice from FAO/WHO then we would be doing a complete turnaround on dietary fibre. But we've picked up from the meeting there is huge resistance to that. So in some ways if you rely on one source of expert advice you are not actually looking across the totality of the evidence.

(Interview, November 2007)

### 6.3 Knowledge Claims and Scientific Techniques: Evidence and Analysis

The Codex has achieved the aim of having an international definition of dietary fibre (albeit with national discretions). The definition was adopted by the Codex

Commission in July 2009. Despite significant differences in the scientific advice used in the negotiations, a compromise has been reached between member governments. Or, in the words of one food industry consultant, the stated definition is “a fudge to keep the various interests happy.” (Personal communication, February 2009). ‘Fudge’ is an apt description of the definition agreed in Codex, given that many questions relating to the use of claims about fibre content in food products remain unresolved. Significantly, no progress was made on the question of appropriate methods of analysis. As detailed in Chapter Five, the methods used to measure the presence of dietary fibre are an important part of the controversy. In this regard two important points can be made about the production of knowledge claims and their relationship to scientific technique in this case. Firstly, scientific techniques have been used by various parties to produce evidence that certain dietary components have certain physiological effects (and therefore might be considered to be dietary fibre). Secondly, an important part of the debate over how to define dietary fibre concerns the scientific techniques used to analyse the fibre content of a given food product. In this way scientific techniques have two important roles in the contention over dietary fibre. They are used to provide insights into what might be considered dietary fibre (evidence of effects) while also being used to analyse the dietary fibre content of food products (analysis of material). The controversy over defining dietary fibre is located in discussions over whether any of these techniques prove anything conclusive about dietary fibre.

The evaluation of scientific techniques used to analyse material has played an important role in the contention. Discussion on the relative merits of particular techniques have turned on the division between AOAC methods and Englyst method (as discussed in Chapter Five). According to Klaus Englyst, the AOAC suite of analytical techniques are weak because they are ‘empirical methods’. By an empirical method he means that:

Ok, well a rational method provides a measurement of a defined component. Essentially this means you do some sort of chemical determination of what is there. An empirical method you are not actually measuring a defined component, what is measured is determined by the method. And the reason why it is an empirical method is because it is gravimetric and you have no way of knowing what is in there. It’s just a recovered weight, a residue, essentially of unknown composition.

(Interview, December 2008)

The assertion here is that AOAC methods are not meaningful; they cannot provide the analyst with a means to carry out an exact measurement of a “defined component” due to the use of gravimetry. As a result, any material identified using an AOAC could contain, according to Englyst, unknown material. In contrast, a “rational method” provides a certain measurement of a known and identifiable component. Englyst suggests that the rational methods measure a defined component. In considering the role of measurement in science, Hacking (1983: 243-244), following Kuhn (1961/1977), suggests that while “Measurements articulate details of known material”, it is also the case that “Experimenters have various motives for measuring. They are rewarded when they devise ingenious systems of measurement.” The rational method described by Klaus Englyst suggests that he regards the Englyst method of analysis as the more accurate technique for measuring dietary fibre. However, accuracy in measurement and ingenuity in measurement is not necessarily the same thing. According to Hacking (1983: 244), the drive for accuracy within scientific measurement can result in the production of “esoteric differences”. By this he means that in trying to achieve greater accuracy in measurement, anomalies can be observed which unsettle scientific consensus. In the case of dietary fibre analysis, the differences are not merely esoteric. They are related to what is believed about appropriate dietary intake. The belief of Klaus Englyst, Hans Englyst, John Cummings and those associated with the FAO/WHO Scientific Update is that dietary fibre should be defined as intrinsic plant cell wall polysaccharides. The emphasis here is upon the belief that “Dietary fibre should be defined to reflect the health benefits of a diet rich in fruits, vegetables and whole grains and not the variable physiological properties or health effects of the various carbohydrate types.” (Cummings and Stephen, 2007: S15). The accuracy of the Englyst method – the rational method – is bound with the choice of concept definition. If the FAO/WHO definition is applied, then the Englyst method would seem well suited to identifying the constituents of dietary fibre.

As detailed in Chapter Five, the Englyst method was not viewed so positively in the draft Codex definition of dietary fibre discussed in 2007. Here the method was described as “complicated” and unsuitable for routine analysis (Codex, 2007a). It was also emphasised that the Englyst method was not used on a worldwide basis. Expressing concern that a scientific technique for measurement is too complicated does not seem to fit with the drive for accuracy described by Hacking (1983). Herein lies the

difference between scientific techniques used for analysis and scientific techniques used to produce evidence. In the case of dietary fibre, the aim of the analyst is to measure the abundance of a known component of a material, while the aim of the researcher is to measure the effect of components (some as yet unidentified) upon the physiology of humans. The analyst is interested in amounts (of known things), the researcher is interested in effects (of known and yet to be identified things). However, analytical methods have to be produced and established. Producers of analytical techniques – such as Hans Englyst and John Cummings – are not content to be sidelined with the task of measuring given their close involvement in research science. Instead, they have firm views about what should be measured and why this should be so, based upon an understanding of the evidence produced by research in clinical nutrition. Their philosophy towards measurement was summed up by a research scientist at Englyst Carbohydrates Ltd: “say what you measure and measure what you see.” (Interview, July 2008). Likewise, their philosophy towards the relationship of science and policy-making can be identified through their active involvement in the submission and elucidation of scientific evidence and advice to regulatory processes.

The controversy over dietary fibre would be much reduced if it were agreed that everything which is not digested in the small intestine of humans should be measured as dietary fibre. Analysts could follow AOAC methods to do this. In fact, food analysts in the UK use AOAC method 985.29 (determination of total dietary fibre by enzymatic-gravimetric method) for food labelling purposes, though not for health claims. Currently, ten different techniques are recognised by the AOAC for dietary fibre analysis. Three techniques quantify the presence of soluble and insoluble polysaccharides, while others deal with identifying the presence of oligosaccharides and resistant starch. As detailed in Chapter Five, the ‘gold-standard’ for dietary fibre analysis, according to Leon Prosky (former President of the AOAC), is AOAC method 985.29. This method, devised by Prosky *et al* (1992), measures soluble and insoluble fibre, giving a value for total dietary fibre. This approach is unacceptable to proponents of the Englyst method. For instance, John Cummings suggests that:

when Englyst analysed the AOAC residue it contained everything under the sun. From the kitchen sink downwards and in variable proportions. It is a hopeless method. But because a lot of money was spent, it was over £1 million on the original ring-trial, and it was devised by a committee. And what the study did to

show it was reproducible, but they never asked what it measured. And they've never tried to do that. Just got some notion of non-digestibility, stew it with some enzymes and make some corrections, that actually is not a good thing to do.

(Interview, December 2008)

The debate over methods from this perspective would seem like a dispute over scientific norms and conventions, as discussed by Merton (1973). The accusation of Cummings is that the AOAC method 985.29 has not emerged from disinterested science and that the values for dietary fibre the method determines do not reflect the true dietary fibre content of a food item. Yet this accusation turns on the definition of dietary fibre. If dietary fibre is agreed to be all carbohydrate polymers which are not digested in the small intestine, then the AOAC could be acceptable.

The controversy over methods would seem a circular debate between agreeing a definition and agreeing on methods which can measure the defined components. In the Codex, a definition has been agreed and so it would seem that negotiation over appropriate methods of analysis will follow. A working group, led by France, has been tasked with advancing discussions on suitable methods of analysis ahead of the 2009 Codex Nutrition Committee. However, the agreed definition of dietary fibre was not produced by resolution within the scientific community. Instead, it was resolved in negotiations in the Codex process (and in many other places, as suggested by the earlier sections of this Chapter). Despite this, the lack of unity evidenced in the dietary fibre case is cited as creating particular problems for regulators (risk managers). As one government delegate, well versed in dietary fibre science, suggests:

It is easier for Codex to move forward on something where there is strong scientific agreement, so if everyone can look at the science and agree to the science then you can build your standard on that. But if we are still debating the science, then Codex isn't necessarily the place where you can resolve the scientific issues.

(Interview, February 2008)

The need for scientific debate to be brought to a conclusion is a pressing one in Codex standard-setting. The longer scientific questions and issues are discussed, the harder the

task faced by government delegates to agree the content of the standard. Importantly, as the delegate above suggests, government regulators are standard builders. Their main task is to be involved in the construction of a standard. However, they cannot do this without recourse to scientific evidence and advice, provided by scientists. Yet, the Codex standard-setting process is viewed as a difficult place in which to discuss scientific issues. Following this, scientific debate cannot be closed in the Codex and so controversy remains on-going.

The relationship between scientific issues and policy-making issues transcends a neat divide between science and policy. It is not possible for Codex standards to be set without invoking controversies which may exist within the science. However, demarcation between science and policy is maintained by the activity of boundary work (Gieryn, 1983). Following the risk analysis paradigm which guides Codex standard-setting procedures, the resolution of scientific disagreement is seen as an activity which should take place outside of risk management arenas such as the Nutrition Committee. According to Codex procedures, the conduct of risk assessment and the formulation of scientific advice ought to result in an acceptable level of scientific consensus over a particular issue. The outcome of the risk assessment can then be presented to risk managers in the relevant Codex committee, who can debate the details of the final standard to be sent for adoption by the Codex Commission. Accordingly, this process proceeds more easily if the science has been settled. The presumption is that scientific fact can be established in isolation from regulatory concerns. In fact, this division is used in the creation of boundaries between science and policy. Reflecting on his experiences of participating in the 2007 and 2008 Codex Nutrition Committees, John Cummings recalls a government delegate asking whether he thought he had compromised his scientific integrity “because I was a risk assessor and they were risk managers and the two should never meet.” (Interview, December 2008).

Despite the rhetorical maintenance of boundaries between science and policy, the building of Codex standards involves the integrated use of various kinds of inputs. Such building work is made easier if the inputs can be agreed, but frequently they have to be negotiated. In considering the relationship between science and technology, Latour (1987) suggests that fact-builders and object-builders share a common problem in ensuring the knowledge claims they employ are convincing. In the case of defining



dietary fibre in the Codex, there are many builders of ‘facts’ and ‘objects’. Conceptualising and stating the relationship between fact and object is of crucial importance to the problems faced by those engaged in setting a Codex standard. In Chapter Two, it was suggested that, for Latour (1987), facts and objects are constructed by fact-builders and object-builders to produce immutable mobiles. Immutable mobiles are those objects and devices containing information which are stabilised over time and then are able to travel and act upon others. Further, a similarity was suggested between the notion of immutable mobiles and the concept of boundary objects as proposed by Star and Greisemer (1989). In particular, the boundary object characterised as a ‘standardised form’ was considered to share many of the qualities comprising immutable mobiles. Both concepts help in analysing the attempts to establish a definition for dietary fibre through the refinement of different scientific techniques. Rather than considering dietary fibre as a given to be identified by a superior method of analysis, the concepts of boundary objects and immutable mobiles draw attention to the mutual construction of such entities between fact-builders and object-builders. Importantly, this construction is a negotiated process with an uncertain outcome.

## 6.4 Conclusions

This Chapter has provided an analysis of empirical material relating to the production of knowledge claims for defining dietary fibre. The analysis comprised two main sections. In Section 6.2, four domains were identified in which knowledge claims over dietary fibre have been produced and have had an important impact upon standard-setting within the Codex. Regulatory activity in the EU pre-dates discussion in the Codex and Section 6.2.1 detailed how attempts to bring together divergent scientific groups were characterised by classic core-set disagreements over dietary fibre science. The impact of discussion within the EU had implications for EU member states, and in particular the UK. As discussed in Section 6.2.2, the UK undertook domestic regulatory science in response to activity within the Codex and as a consequence of the competencies afforded to the EU on the definition of dietary fibre. As the major negotiating partner of the European Commission within the Codex, the actions of the US – detailed in Section 6.3.3 – were more circumspect. Domestic regulatory processes demanded that the US remained non-committal to the definition being negotiated in the Codex and this was

reflected in meetings and submitted comments. Finally, scientific advice produced by FAO/WHO was considered in Section 6.3.4. Within this process ILSI was an important knowledge broker, becoming the focus for discussion over FAO/WHO scientific advice which could not be elaborated within the formal standard-setting process, but was to prove crucial in enabling a final agreement to be reached.

The second major section in the Chapter – Section 6.3 – focused upon the role of scientific techniques in the production of knowledge claims. Here it was argued that contention over the analytical techniques used to identify and measure dietary fibre could not be resolved on the basis of science. Despite the wish of government delegates to proceed on the basis of science, such a situation could not be achieved due to strong scientific disagreement. Measurement, in one respect, involves the identification of esoteric differences (Hacking, 1983), but also involves differences in assumption about the practical consequences of measurement. In attempting to define dietary fibre, disagreement over measurement encapsulated disagreement over the ability of food companies to make nutritional claims for certain products. In this respect the meaning of a nutritional category became the focus of argumentation. Such disagreement is an example of what Weinberg (1972) has termed a trans-scientific problem.

The following chapter builds upon the insights of Chapter Four, Five and Six by considering the implication of the empirical material for understanding how standard-setting occurs within the Codex. The discussion proposes three main arguments. Firstly, Codex standard-setting follows a methodology. Secondly, defining dietary fibre was a technical controversy and so was amenable to the creation of a boundary object as a means of obtaining a settlement. Thirdly, scientific and technical expertise plays an important role in the conduct of agri-food governance and requires further conceptualisation through empirical investigation.

## **Chapter Seven – Standard-Setting: Methodologies and Boundary Objects**

### **7.1 Introduction**

The previous three chapters have dealt with empirical material concerned with the agreement of a definition for dietary fibre in the Codex Nutrition Committee. The process of negotiating a definition for dietary fibre within the Codex system was set out in Chapter Four. Here the interrelationship between the construction of a scientific fact and the construction of a Codex standard was demonstrated through the building of a definition for dietary fibre. In Chapter Five, the scientific debate over dietary fibre was analysed. A core-set of scientists were identified as contributing to an on-going controversy over the appropriate definition of dietary fibre and methods of analysis. The controversy could not be resolved on the basis of science alone. However, the contentious science base did not prevent the articulation of scientific advice. In Chapter Six, diverse sources of scientific advice were discussed and in particular the knowledge claims produced in the European Commission, UK, US and the FAO/WHO were considered. It was demonstrated that scientific advice was produced within these contexts in direct correspondence with standard-setting in the Codex.

In this chapter, three main arguments are detailed. Firstly, as discussed in Section 7.2, Codex standard-setting is a distinctive kind of international policy-making. Specifically, Codex standard-setting is a methodology intended to facilitate agreement and the diffusion of regulatory systems. The use of scientific advice as a basis for discussion means that science becomes the arbiter of competing interests and the language through which negotiations are conducted, thus ensuring policy discussions have only a limited scope. However, the division between the provision of scientific advice and the interpretation of this advice for the production of a standard is not stable and is open to challenge through the active maintenance of boundaries between science and policy. Despite the central role of the risk analysis framework in Codex standard-setting, risk, and in particular highly specific risk assessment, is not necessarily

mobilised as a core concern. In order to manage such a process, Codex standard-setting follows a distinctive methodology.

Secondly, as detailed in Section 7.3, the controversy over dietary fibre is conceptualised as a technical controversy. When dealing with technical controversies it is likely that the issue in question will become a boundary object. Technical controversies are those controversies located within regulatory processes, which build steadily over time and often over many years, and are eventually resolved by institutional pressures requiring a final outcome. They are distinct from controversies which, although subject to regulatory debate, have a wider public input. Often, policy-making around scientific controversies involves public interest groups, environmental groups and citizen groups, as in decisions over nuclear power or agricultural biotechnology. The likelihood that technical controversies will appear in the Codex system is increased by the methodology of Codex standard-setting. In the Codex system, technical controversies have time to build and develop, as less contentious elements of the standard are constructed first and held in place by the Codex procedure. With increasing concern to resolve the technical controversy, a large body of competing scientific advice accumulates. This advice is not, on its own, capable of resolving the controversy. In order to bring a sense of finality to a technical controversy, it is likely that a boundary object will be formed, around which various interests can co-operate. The boundary object is robust enough to be identifiable as a distinct entity, but flexible enough to enable multiple interpretations. In the case of dietary fibre, a definition was produced which enabled the completion of the Codex 'Guidelines for the Use of Nutrition and Health Claims' (the Claims standard). The definition provided a detailed text on the qualities of dietary fibre, but left unresolved scientific questions of evidence of physiological effects and methods for analysis. By referring these scientific issues for further discussion, the objective of providing a definition for the Claims standard was achieved. However, by producing dietary fibre as a boundary object, the scope for further discussions has been increased.

The implications of science-based food standard-setting for the governance of the agri-food system are taken up in Section 7.4. Here it is argued that international food standard-setting is a highly methodological form of agri-food governance. Such a process is recognised by food companies as an opportunity for regulatory reform which

can create opportunities for market differentiation. In this respect food companies, who have an active interest in launching new food products, can become closely involved in the creation of new categories and entities, such as revised nutritional categories. The ability for companies to become market leaders in product development is at stake, due to the importance attached to nutrition and health claims. Scientific advice from EFSA and ILSI supports such an approach to market creation. A study undertaken on behalf of Tate and Lyle on consumer attitudes to dietary fibre suggested that, despite relatively low levels of interest in dietary fibre, it was regarded as a beneficial component of food (Tate and Lyle, 2008). At a conference in 2009 it was suggested by a Tate and Lyle representative that it would be possible to generate public interest in products high in dietary fibre and to differentiate such products within the marketplace (Personal note, March 2009).

Such an approach to product development suggests a close interrelationship between standard-setting, product specification and marketing activity, in keeping with the arguments of Stanziani (2007). In this sense, international food standards are important instruments of political economy – they are not *only* produced to restrain unwanted impact upon the public. Instead, they are *also* instruments which can be used to create new markets and in doing so become a driver for new products. However, by maintaining a rhetoric of scientism, Codex standards constitute an institutionalised depoliticisation of such issues. The negotiation of notions of food quality and safety is therefore reduced to a scientific, technical discussion despite the political motivations for standard-setting activity and the mobilisation of knowledge claims. As a result Codex standard-setting struggles to maintain a coherency around depoliticised decision-making, as the very issues under discussion constitute changing political economic environments in the agri-food sector.

The interrelationship discussed above means that questions of scientific evidence and advice – involving the mobilisation of knowledge claims – have an important influence upon economic activity and policy-making. The following section examines the manner in which such knowledge claims are treated within the standard-setting process.

## 7.2 Codex Standard-Setting as a Methodology

Debates over scientific evidence and advice are crucial elements of standard-setting in the Codex. As Majone (1984) has stated – drawing upon Weinberg (1972) – standard-setting is often a trans-scientific activity. While the language of science is used in standard-setting, the negotiation of standards involves more than science and therefore cannot be concluded on the basis of science alone. In order to deal with trans-scientific issues, Codex standard-setting proceeds as a methodology. In this sense the process has a technical quality. By working as a methodology, the standard-setting process can respond to contention and controversy without instability. Although a methodological orientation allows for relative stability in the process, it may also introduce path-dependency and can be criticised for failing to accommodate new interventions. Codex methodology has to deal with conflict over scientific advice, which may be considered as controversial to the scientists involved and to the member government delegates who work to agree a standard.

In the case of defining dietary fibre, science does not enter the standard-setting process as the outcome of debates settled in separate, scientific domain. The implication of the active discussion of science within the standard-setting process is that scientific knowledge claims become the focus of intense scrutiny, though they do not necessarily provide the basis upon which the negotiation process can be settled. Instead, debate over scientific advice is a constituent of the standard-setting process and can, in turn, drive the production of further scientific activity. The result is an increasing concern to undertake regulatory scientific work amongst member governments and international organisations. Standard-setting can therefore produce controversies over science even as it attempts to harness science as a basis for discussion. As Rothstein *et al* (2006) discuss, a cycle is initiated whereby increased regulatory activity to manage risks and to set regulation has the effect of instigating further regulatory science, which in turn identifies further questions and uncertainties for regulators.

Such a situation, with a high-level of iteration between science and policy-making, poses particular problems for the concept of epistemic communities. To restate, and following Haas (1992; 2004), epistemic communities are transnational networks of scientists who share an authoritative claim to knowledge. More specifically, they share

normative and principled beliefs, causal beliefs, notions of validity and a common policy project. Epistemic communities are said to be influential in international policy-domains which require scientific and technical input. However, the assertion of an authoritative claim to knowledge is not straightforward in the Codex standard-setting process. Even if a recognised knowledge claim can be established, it does not necessarily follow that this knowledge claim will be recognised as authoritative and so resolve the process. The agreement of a knowledge claim amongst scientists cannot happen outside of the standard-setting process and then be used to settle the process. To conceptualise the role of scientific advice and input in standard-setting in this way is to misunderstand the process of standard-setting.

Standard-setting in the Codex is said to follow a risk analysis framework, which sets out the relationship between scientific advice and policy-making. Within this framework, risk assessment is the scientific domain of the standard-setting process in which evidence is produced and advice is offered to the risk managers who must agree the final form of a Codex standard. Risk assessment in the case of dietary fibre comprised a Scientific Update; a review of existing studies. The review, conducted by a group of experts at the request of the FAO/WHO, was not conducted as a result of a demand for risk assessment by risk managers in the Codex Nutrition Committee. Instead, risk managers were negotiating a definition for dietary fibre without the direct input of risk assessment by a FAO/WHO expert group, although FAO/WHO representatives had made reference to existing work on carbohydrates. In short, risk managers in the Nutrition Committee felt able to develop a definition for dietary fibre without recourse to a risk assessment by FAO/WHO. Risk assessment, when it was produced, came in the form of a scientific review. The term risk assessment, in this case, does not refer to a highly quantitative and specific analysis but instead captures the general provision of scientific advice. Using the term in this way means that risk assessment no longer adheres to the original focus upon reducible problems such as those identifying mechanical faults in aircraft (Wynne, 1992). Instead, risk assessment becomes a signifier of scientific rigour in standard-setting process, suggesting a robust and distinct domain of scientific evidence production.

The term risk assessment as applied to broader science-based policy-making has meaning which is not necessarily reflected in the activities undertaken. Risk

assessment, rather than a highly specific and quantitatively exact analysis, is applied to a potentially wide ranging set of activities. Moreover, in the case of dietary fibre, risk is not mobilised as a concept within the debate. This is despite the concern of some scientific work on dietary fibre with the physiological effects of fibre, in particular the possible reduction in colorectal cancer and in food energy intake (with implications for obesity). According to the FAO/WHO review, epidemiological work suggested a link between dietary fibre intake and health benefits, but no conclusive evidence for causal mechanism and effects could be demonstrated.

The lack of discussion of risk in the contention over dietary fibre was a consequence of the focus upon identifying the constituent substances of fibre, the appropriate methods of analysis and from the accepted claim that non-starch polysaccharide (NSP) is beneficial to human health. The controversy over dietary fibre emerges from concern over the breadth of the definition and the inclusion of substances other than NSP within a total for dietary fibre in a given product. The risk issue, in the widest sense, is the dietary intake and health of food consumers. Yet, in trying to agree a definition of dietary fibre, it was suggested that any agreement should not be reached on the basis of trying to achieve high consumption of NSP amongst the public. As such, the general risk issue was deemed too diffuse for the Nutrition Committee to address. As a result, negotiations focused upon those components other than NSP which could be considered to be dietary fibre. In the case of FAO/WHO advice, the focus of debate shifted between an emphasis upon the broader public health benefits of the dietary fibre concept and an attempt to provide an exacting, chemical definition of fibre. In the case of the European Commission and ILSI, an emphasis was placed upon the characteristics of 'new' components which should be considered as dietary fibre as they offered a benefit to public health and/or shared certain properties with NSP (primarily indigestibility in the small intestine). In this way, the focus of debate moved away from public health rationales and towards the physiological and chemical properties of the substances.

So far, this section has suggested that, despite the configuration of the Codex risk analysis framework, risk assessment is not a discrete domain of scientific activity. Further, the notion of risk itself was not mobilised within the dietary fibre controversy. Therefore, the provision of scientific advice and the notion of risk – both defining



aspects of Codex risk assessment – are dependent upon the context in which standard-setting takes place and the issue in question. As suggested, scientific controversy, when it arises, is a constituent of the standard-setting process and activities undertaken as part of risk assessment are located within the controversy. Attempts to articulate divisions between science and policy-making are undertaken on a rhetorical basis, as the identification of the scientific and the political becomes an outcome of negotiation. In this way the division between science and policy-making is a product of boundary work undertaken by participants in the process (Gieryn, 1983). While some participants in standard-setting are identified as risk managers – they are representing member governments – this does not mean that their interventions and discussions are undertaken on the basis of agreed science. Discussions over scientific advice in the Nutrition Committee suggest that when a risk assessor is not present in the debate, competing sources of advice achieve a greater prominence. Scientific advice in the Codex becomes an issue for discussion amongst risk managers, who not only engage with each other but also engage with scientific experts. The coherency of risk assessment as a defined procedure conducted by a group of experts is challenged by the presence of diverse sources of advice and in such circumstances, the FAO/WHO struggles to assert primacy. Moreover, the standard-setting process accelerates ahead of new regulatory science, thereby reducing the opportunity for new scientific advice to influence debate.

While the use of scientific advice within the Codex is problematic in a context of controversy, the standard-setting procedure requires that standards be constructed on the basis of science. In the case of defining dietary fibre, there is no single authoritative knowledge claim. Even if one could be found, the science itself has been produced by the activities of regulatory science; that is the science has emerged out of concern over the setting of national regulation, partly in response to negotiations occurring at the international level. Further regulatory science is thus conducted in response to on-going debates in the Codex, increasing the sources of evidence to be debated. In such a situation, the Codex standard-setting procedure could quickly break down given the proliferation of scientific advice. This would mean that a consensual outcome could not be established and the standard-setting process would eventually fail.

Failure to agree a standard is something which the Codex methodology is designed to avoid. The method of agreeing a standard in the Codex is configured to allow for the gradual transition of standards through more detailed levels of iteration, with the agreement of interested parties. In this way progress can be maintained, as standards are seen to advance towards their eventual adoption. The agreement over dietary fibre, despite being discussed over several years, could have been seriously impacted by the scientific advice offered by the FAO/WHO. This advice contradicted the definition as had been worked out in the Codex Nutrition Committee. Some member governments, who had not contributed significantly to the debate until this point, voiced the opinion that the FAO/WHO advice should be central to the discussion. However, the discussion of dietary fibre had reached a stage in which major revisions to the standard would be viewed as undoing the work which had already taken place and endangering completion of the task as requested by the Codex Food Labelling Committee. Also, and relatedly, the FAO/WHO advice called for a far simpler definition of dietary fibre than that developed in the Codex definition – a definition considered overly restrictive by food industry groups. Therefore, adopting the FAO definition would limit the ability for nutrition claims to be made on the basis of a high fibre content for food products.

The analysis suggests that the standard-setting process in the Codex is structured to maintain the focus of negotiations upon narrowly defined issues which should be supported by scientific evidence and advice. In working out a definition for dietary fibre, broad and inconclusive concerns such as public health risks were not considered relevant to the elaboration of the definition. Instead, debate focused, using scientific language, upon an issue which could not be resolved by science alone, namely the selection of components which could be considered to be dietary fibre.

Related to the question of definition is the question of methods for analysing dietary fibre. Again, in order to maintain the focus and momentum of the standard-setting process, the discussion of methods for analysis was separated from discussion of the definition. In this way the Codex produces discussions which may not have been possible without the use of a methodology. By separating aspects of a standard for discussion, it is possible that more detailed discussions can be initiated about core issues which require negotiation. Agreeing a definition of dietary fibre could not have been undertaken without first ensuring that other elements of the Claims standard had been

agreed and sent for adoption. Once sent, these elements were no longer the concern of the Nutrition Committee (unless returned for further discussion). By proceeding in this way the standard-setting process creates the opportunity for interested parties to anticipate the discussion of a contentious issue and also allows more time to be devoted to its discussion within a committee.

Elements of the Claims Standard were sent to the Codex Commission for adoption in order to focus debate upon the definition of dietary fibre, which emerged as a problematic issue. The Codex standard-setting procedure requires that draft standards be agreed in subsidiary committees, such as the Nutrition Committee, and then sent to the Codex Commission for adoption. In trying to agree the Claims Standard, some elements of the standard were agreed and sent for adoption, while others were held back for future discussion. In order to steadily build completion of a difficult standard, the Codex methodology compartmentalises standards in order to allow progress to be made. Compartmentalising a standard also focuses discussion upon a particular aspect of the standard. This is important if elements of a standard prove difficult to agree. Member governments can discuss one aspect through to resolution, without becoming involved in more disparate or contentious discussions.

The act of limiting the basis of discussion to achieve an agreement is a common one in the Codex methodology. The basis upon which discussions began within the Nutrition Committee was set by the Codex Food Labelling Committee, despite concern within the Nutrition Committee that the standard may conflate health claims and nutrition claims. The Codex methodology operates through a hierarchy of referrals, with some committees – such as the Food Labelling Committee and the General Principles Committee – enjoying a more senior position than others. Of course, some committees may produce standards with implications for others committees, or request input from other committees. However, the more general the topic area covered by the committee, the more likely it is to request information from a more specialised committee. In this way, standards are initiated in one place, but take inputs from other committees. In the case of the Claims standard, the items to be discussed by the Nutrition Committee – the values for nutritional categories – could not be brought to a conclusion without further separation of activities. Setting a definition for dietary fibre emerged from the methodology of separating controversial aspects of the discussion.

Viewed in this way, the Codex standard-setting procedure is a methodology for ensuring the production and finalisation of a standard, in this case the Claims standard. The Codex methodology comprises a number of elements. Some, as discussed, are formal procedures such as the step-wise process for elaborating standards. Likewise, the risk analysis framework provides a structure for the relationship between scientific advice and the setting of standards. Compartmentalising standards into distinct agenda items has the effect of focusing debate upon narrowly defined issues, which taken collectively form the standard in question. The methodology of standard-setting also employs devices intended to allow for the substantiation of facts. An important device in this respect is the defining of objects. By agreeing a definition – which once had various and uncertain meanings – regulatory systems can practically interact. The act of defining, as a device within a methodology, has the effect of bringing some things into the definition and leaving other things outside. Although defining dietary fibre had been an issue of scientific contention before discussion began in the Codex, within the Codex methodology establishing a definition is a different task than that undertaken by core-set scientists. Defining, when conceptualised as a methodological device, forces interactions between interested parties towards an outcome. In contrast, defining amongst core-set scientists becomes an issue of further exploration and debate. Defining within a scientific context is thus oriented around exploration, whereas defining within a methodology is oriented around resolution. In this way, defining dietary fibre in the Codex system does not equate to simply identifying the relevant carbohydrates, but instead is a device by which regulatory systems are forced to interact.

Although the Codex methodology can use defining as a device to finalise a standard, in order to do so it is necessary to untangle questions of defining from other issues. For dietary fibre, an important element of the controversy was the agreement of suitable methods for analysing dietary fibre. Despite this, the scope of dietary fibre was agreed without reaching an agreement on the suitable methods for analysing the substances comprising dietary fibre. The recognition of particular methods would have an impact upon the levels of dietary fibre measured in food products. Further, a definition incorporating extracted and synthetic carbohydrate polymers would require methods capable of measuring these components. As suggested in Chapter Five, the draft Codex definition of dietary fibre had been elaborated to include a list of suitable methods for

analysing dietary fibre. All eleven methods listed were Association of Analytical Communities (AOAC) recognised methods and measured a diversity of food components. The list of methods specifically stated that the Englyst method was not deemed suitable for routine analysis and was not recognised on an international basis.

The agreement of a final definition for dietary fibre and the apparent dismissal of the Englyst method as a suitable method of analysis created a curious tension. As the final definition of dietary fibre became more complex, with a greater array of components considered to be part of the definition, the methods of analysis to be used were judged on their relative simplicity. Two AOAC methods in particular were deemed suitable for measuring total dietary fibre, with the remaining nine to be applied to measure specific components such as fructans and polydextrose. The question of agreeing suitable methods of analysis seemed, from the content of the draft definition, to be straightforward. However, no categorical evidence was produced in support of the claims that the Englyst method was an unsuitable method for the measurement of dietary fibre content in foods. The issue over methods of analysis could not be resolved while discussions were taking place over the definition of dietary fibre, as both aspects were deemed controversial. Further, the decisions over which methods to include and which to exclude could not be resolved on the basis of science given the lack of evidence.

Methods for measurement, according to Hacking (1983), can unsettle scientific consensus and provoke new controversies. In attempting to deliver tools for increasing the accuracy of observations, scientists ensure that new differences emerge between entities. Hacking suggest these difference may be esoteric. While this is true in some instances, the differences may not be only esoteric; they are also material. For dietary fibre, the specification of methods of analysis implicitly entailed a definition for the components comprising dietary fibre. For the Englyst method, dietary fibre was considered to be principally NSP. For the AOAC methods, dietary fibre was considered to be NSP plus other components such as resistant starch and oligosaccharides. No single method could carry out the analysis of all constituent parts in a single analytical procedure. As discussed by some dietary fibre scientists, the term 'dietary fibre' imposed difficult conditions upon deciding how to characterise non-digestible carbohydrate components of food which had beneficial effects on human health. The

notion of dietary fibre, though considered to be a nutritional category with important implications for public understanding of food products, imposed difficulty in analysing diverse food components. As a result, two strategies emerged. The first was to restrict dietary fibre to the NSP classification. The second was to open up dietary fibre to include NSP and non-digestible components. In negotiating the text comprising the definition of dietary fibre, discussions of the methods of analysis were used in the scientific advice offered by the FAO/WHO. The review stressed that dietary fibre ought to be defined on the basis of chemistry rather than physiological effects, as chemical properties could be measured and defined more easily. A definition for dietary fibre would have to correspond to an identifiable component; in other words, NSP.

In this section it has been argued that the methodology of Codex standard-setting ensured that discussions over the relationship between the definition of dietary fibre and the methods of analysis were restricted in scope. In this way, activity within the Nutrition Committee was focused upon agreeing the constituents of dietary fibre. Definition – as applied as a technical device within the Codex methodology – served to assist in the structuring of the process by ensuring negotiation remained focused upon a smaller set of issues. Efforts to reach an agreement on the definition of dietary fibre, following the methodology, ensured that other elements of the controversy were not addressed. The technical quality of Codex standard-setting ensures that discussion can be compartmentalised and focused upon the issue most pertinent to the conclusion of debate.

As will be discussed in the following section, the lack of wider public involvement assisted in the application of the methodology. Such a situation meant that dietary fibre, in order to be defined, had to become a boundary object.

### 7.3 Technical Controversies and Boundary Objects

Although Codex standard-setting is a methodology to ensure standards are agreed, this does not mean that controversies are necessarily settled. In order to bring negotiations to a conclusion, and to produce a final text which can be adopted by the Codex

Commission, scientific contention has to be overcome. However, in order to produce a standard, it is not necessary for scientific contention to be resolved. So long as the final standard can adequately satisfy the competing knowledge claims at work in the standard-setting process, the process can be finalised. This is particularly true when scientific controversy is not located within a wider public dispute.

The absence of a wider public involvement in the standard-setting process is evidenced in the definition of dietary fibre. As such, the controversy over dietary fibre can be conceptualised as a technical controversy. A technical controversy occurs without any significant wider public attention and builds slowly within specific regulatory and scientific domains. Other controversies with a significant scientific component – such as over nuclear power or agricultural biotechnology – while posing significant regulatory questions – do not conform to this mode of controversy. Although policy-making over publicly contentious issues is frequently criticised for recognising a narrow base of expertise, this does not mean the policy-making process is necessarily unresponsive. As noted in Chapter Two, demands to open up policy-making to diverse sources of expertise have increased in recent years. However, in the case of technical controversies, there is little public awareness of the questions being addressed and little mobilisation of wider interests beyond a narrow base. Technical controversies, while concerned with issues with implications for the public, are subjected to little public debate and are not the focus of significant mobilisation by public interest groups. However, industry groups with a strong interest in the outcome of regulatory reform may play a significant role in the negotiation of technical controversies.

The lack of wider public involvement in the definition for dietary fibre meant that the agreement of a definition took place between leading scientists, government delegations, industry groups and the FAO/WHO. In areas of agri-food governance characterised by scientific and public contention – such as the safety of food products containing genetically modified components – a large and diverse source of scientific evidence and advice may prove relevant to the policy-making process (even though there may be situations whereby certain advice is deemed more important than others). Codex standard-setting often focuses upon more narrowly defined issues, with an expectation that the sources of scientific evidence will be more limited and less controversial. However, in the case of dietary fibre, a relatively small group of

scientists – a core-set (Collins, 1981) – have been involved in the debate over the scientific evidence and producing a single, conclusive outcome (perhaps based on a knock-down argument) has not proved possible. This situation is compounded by the trans-scientific quality of standard-setting. While the controversy over dietary fibre has been characterised as one over scientific evidence and advice, the disagreement turns on questions which science cannot necessarily answer.

The general issue encapsulated by the contention over dietary fibre is one of public health and food production and consumption. Nutritional claims for food products will be made in relation to the agreed definition of dietary fibre and the level of the claim measured by agreed methods of analysis. However, while this issue may have wider public implications, it does not exhibit the characteristics typical of agri-food issues which provoke public involvement. Although periodic crises and events in the agri-food system have served to focus public attention – leading to regulatory reforms in some instances (Donaldson *et al*, 2002) – technical controversies do not exhibit such high profile characteristics. The methodology of Codex standard-setting ensures that institutional questions are not provoked by contentious standards. As a result, the forms of expertise relevant to the negotiation of technical controversies are not open to sustained scrutiny.

The forms of expertise brought to bear upon the settlement of technical controversies are characterised by high levels of scientific or technical competency. In this context, technical competency refers to the knowledge and understanding of the Codex standard-setting methodology possessed by experts and their ability to operate within trans-scientific domains. Scientific experts, those with scientific credentials in the area of dietary fibre – from a physiological and methods perspective – were important actors in the negotiation of a definition for dietary fibre. Similarly, technical experts in the Codex methodology were active in the debate. Some experts could claim competency in both the scientific field of dietary fibre and the technical field of Codex methodology (for example government delegates with a background in dietary fibre science). Others were positioned as brokers of expertise and were concerned with the transmission of knowledge between scientific and technical experts (for example representatives of ILSI). However, it is important to recognise that not all participants in the Nutrition Committee could claim to be one or more of these forms of expert. In part, the



constitution of technical expertise in the Codex methodology emerges from having an interest or commitment to the end result of debates. By not having a rationale for engagement in the standard-setting process, some member governments do not participate fully in negotiations and therefore fail to develop technical expertise. A lack of technical expertise compounds their marginalisation within the Codex methodology.

In the case of a technical controversy such as dietary fibre, it can be argued that the problem of extension recognised by Collins and Evans (2002) in Chapter Two, is of a different kind. They suggest that expertise can not be unproblematically extended to all actors. In considering standard-setting in the Codex, two aspects are relevant to this proposition. Firstly, being privy to the methodology of standard-setting – in this case having a seat at the Nutrition Committee - does not lead directly to the development of expertise in standard-setting. Partly, expertise in standard-setting, particularly in technical controversies, emerges from having meaningful participation in the negotiation. Participation in negotiation is the result of two kinds of relevancy: that the issue in question has relevancy to the actors involved and that the actors involved are seen as relevant by other actors involved. Without this kind of participation, expertise remains unarticulated and therefore absent. Secondly, and relatedly, if such limited forms of expertise are exhibited by those merely privy to the standard-setting process, the problem of extension is again in evidence, but this time also applies to those on the inside of technical decision-making. Jasanoff (2003) suggests that controversial policy environments entail a questioning of the authority of expertise and experts. Applying this critique to technical controversies involves interrogating the circumstances which give rise to the lack of expertise conferred upon participants in the standard-setting process, and the dominance of others who are able to enjoy relevant participation.

Involvement in the negotiation of a definition of dietary fibre within the dialogue of the Nutrition Committee – a technical controversy – was closely associated with the delegations of the European Commission, the US, Australia, Canada and the representatives of the FAO/WHO. Other member governments offered comments, but offered noticeably fewer interventions within the Nutrition Committee itself. However, for some member governments, the advice of the FAO/WHO was considered to be representative of their own position and so no further involvement was necessary. This conferred strong scientific expertise (authority over the science of dietary fibre) and

technical expertise (active participation in the negotiation of the definition) upon the FAO/WHO. For these member governments, the problem of extension was not an issue; instead they conferred expertise upon the FAO/WHO. Not only did the FAO/WHO assert scientific expertise by carrying out an expert review, published in an academic journal, but some member governments represented in the Nutrition Committee recognised the expertise of the scientists engaged in this exercise as authoritative. The recognition of such claims to knowledge was not the product of sustained engagement in the scientific controversy, but instead rested with understanding that the FAO/WHO offered advice on the definition of dietary fibre and so articulated a concern with public health. Such an articulation could not be found in other sources of advice.

Support for the FAO/WHO advice and definition of dietary fibre by some member governments emerged alongside the strong rejection of this advice by other member governments. For these reason no epistemic community, in the sense used by Haas (1992), could be said to exist. An impasse seemed to have been reached in which, broadly speaking, two main kinds of argument were proposed. One argument spoke in favour of a limited definition for dietary fibre, the other in favour of a broader definition for dietary fibre. Yet in 2008 the Nutrition Committee finalised a definition for dietary fibre and sent this definition for adoption by the Codex Commission. An agreement had been reached without a final resolution of the conflicting scientific advice offered by the scientific and technical experts involved in the process.

The final definition of dietary fibre adopted in the Codex Commission is shown on the following page:

**GUIDELINES FOR THE USE OF NUTRITION CLAIMS: TABLE OF CONDITIONS FOR  
NUTRIENT CONTENTS (PART B) DIETARY FIBRE**  
(At Step 8 of the Procedure)

COMPONENT	CLAIM	CONDITIONS
<b>B. NOT LESS THAN</b>		
Dietary Fibre	Source	3 g per 100 g* or 1.5 g per 100 kcal or 10 % of daily reference value per serving**
	High	6 g per 100 g* or 3 g per 100 kcal or 20 % of daily reference value per serving**

\* Conditions for nutrient content claims for dietary fibre in liquid foods to be determined at national level.

\*\* Serving size and daily reference value to be determined at national level.

**Definition:**

Dietary fibre means carbohydrate polymers<sup>1</sup> with ten or more monomeric units<sup>2</sup>, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
- synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

**Methods of Analysis for Dietary Fibre**

→ To be agreed.

<sup>1</sup> When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis : Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately "associated" with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysacchrides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

<sup>2</sup> Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

*Figure 7.1: Adopted Codex Definition of Dietary Fibre*

The conclusion of the negotiation over the definition of dietary fibre did not require that scientific controversy be resolved. According to Collins and Evans (2002: 241):

Decisions of public concern have to be made according to a timetable established within the political sphere, not the scientific or technical sphere; the

decisions have to be made *before* the scientific dust has settled, because the pace of politics is faster than the pace of scientific consensus formation. Political decision-makers are, therefore, continually forced to define classes of expert *before* the dust has settled – before the judgements of history have been made.

The suggestion here is that a political sphere exists which operates at a speed which is of a different kind to that inherent to scientific debate. In the case of Codex standard-setting such a claim is problematic. As detailed in the previous section, standard-setting in the Codex is a technical activity; it operates according to a methodology. This is not to say the methodology is without political content. Rather, standard-setting in the Codex incorporates scientific controversy by managing pace, by slowing down the process. As a method for coping with disagreement this can prove beneficial by ensuring a resolution to contention. However, it does not guarantee that a resolution will be achieved. For technical controversies, the lack of public interest means that scientific and technical forms of expertise will be brought to bear on the issue, even if those experts involved cannot agree on conclusive evidence and authoritative advice. In such a situation, resolution has to be achieved by other means.

In order to deal with contention over defining dietary fibre, dietary fibre – as an object to be defined – had to be made a boundary object by those negotiating the definition. As stated in Chapter Two, and following Star and Griesemer (1989), a boundary object is a focus for co-operation by different interests. The boundary object possesses enough coherence to be regarded as an identifiable entity, but also possesses enough flexibility to allow different interests to retain their own interpretations of the object. In the production of a boundary object, agreement over the form of the object becomes more important than consensus over science. Accordingly, consensus over science is not necessary for cooperation, as the flexibility of the boundary object allows for divergent interpretations. As a boundary object, dietary fibre in the Codex came to exhibit a number of characteristics. Firstly, consensus existed amongst all interested parties that NSPs should be recognised as dietary fibre. This aspect of the definition was not negotiated as no objections were made over their inclusion. In this sense, dietary fibre retains coherency, as NSP forms the core property of the object, even though NSP is not explicitly mentioned in the definition. Instead, reference is made to a category of carbohydrate polymers found naturally in food as eaten. These polymers have ten or more monomeric units and are not hydrolysed by enzymes in the small intestine. For

other categories of carbohydrate polymers, the definition is more ambiguous. Other categories included in the definition are carbohydrate polymers – conforming to the notions of polymer length and hydrolysis mentioned above – which have been extracted from raw materials (plants) and those which have been synthesised. The inclusion of both categories of carbohydrate polymer was deemed contentious. Both extracted and synthesised carbohydrate polymers have undergone a process, and as such are used in the production of processed foods. The concept of dietary fibre as proposed by Burkitt and Trowell was articulated as a category of food which had not been subject to significant processing techniques. Including carbohydrates which had been extracted from plants – physically, enzymatically or chemically – clearly contravened this notion. The inclusion of synthesised carbohydrate polymers seemed even further from the original dietary fibre concept. However, both these categories of carbohydrate polymers were included in the definition.

In order to maintain co-operation over defining dietary fibre between the interested groups, the extracted and synthesised carbohydrate polymers were included with a proviso. In order for extracted and synthesised components to be regarded as dietary fibre, a physiological effect of benefit to health must be demonstrated. Here, scientific evidence must be produced in support of such effects and the evidence be recognised by “competent authorities”. This improvisation in the definition – the inclusion of a requirement for physiological evidence – is a key instrument in maintaining co-operation. It is also a central element of dietary fibre becoming a boundary object. By requiring further scientific evidence to be produced on the physiological effects of the controversial carbohydrate categories, the Codex definition for dietary fibre displaces controversy into other institutions. In doing so, the standard-setting methodology maintains its coherency by ensuring that text can be agreed upon, while allowing different interpretations of the parameters of the definition.

Co-operation over the categories of carbohydrate polymers comprising dietary fibre has not resulted in a resolution to the controversy. The continuation of the controversy is also evidenced by a second aspect of the articulation of dietary fibre as a boundary object, concerning the length of polymer chains. In the 2007 draft definition, for carbohydrate polymers to be considered as dietary fibre they were required to have a polymer chain at least three monomeric units in length. The definition in 2008 stated

that for dietary fibre, polymer chains should not be shorter than ten monomeric units. However, a footnote to this stipulation suggested that national authorities could take a decision on whether to include carbohydrate polymers between three and nine units in length. Again, flexibility had been introduced into the boundary object of dietary fibre in order to encourage agreement.

In discussing the concept of boundary objects, Garrety (1997) suggests that for long-standing and persistent scientific controversies nature remains elusive and cannot enable actions capable of resolving the controversy for humans. As such, the production of boundary objects involves the attempt by humans to resolve ambiguity over scientific facts and entities. However, actions to address ambiguity are not merely methods for dealing with an unsettled scientific fact, but are also a response to institutional and material concerns as suggested by notion of co-production (Jasanoff, 2004). Producing dietary fibre as a boundary object within the Codex was primarily a means by which discussion could be brought to a close and the Nutrition Committee could complete work on the issue. However, disagreement over the parameters and composition of dietary fibre could not be resolved. In order for the methodology of Codex standard-setting to be successfully applied, dietary fibre had to become a boundary object and exhibit flexibility in interpretation. In turn, this implied that the methodology of Codex standard-setting could not guarantee an outcome which would result in regulatory harmonisation. Instead, national governments were afforded discretion over the treatment of oligosaccharides, while extracted and synthesised carbohydrate polymers were to be the subject of further scientific activity. In consequence, neither natural factors, produced by scientific activity, nor social factors, produced by institutional configurations, could be ascribed decisive causality. The interplay of scientific advice and methodology ensured that, while standard-setting was brought to a conclusion, a decisive definition was not produced.

As Star and Griesemer (1989) note, consensus is not a necessary condition for the conduct of successful activity. Agreement over the boundary object becomes more important than a pre-occupation with consensus over an authoritative knowledge claim, given the difficulty in formulating a single position from diverse perspectives and interpretations. Although dietary fibre, as a boundary object, is flexible enough to allow interpretations, it remains robust enough to be identified as a distinct object through the

definition as stated in the text of the Claims standard. The finalisation of the definition into the text of a Codex standard gives it a recognised form and authority. Once agreed, the text is a reference point for all future discussion of dietary fibre, whether at the international or national level.

The construction of dietary fibre as a boundary object emerged as a response to the path-dependency of the Codex methodology. A draft definition for dietary fibre was set out at an early stage in the discussions and introduced a framework for the definition which prompted disagreement. Despite attempts by ILSI to co-ordinate scientific evidence supporting the draft Codex definition, no consensus could be formed. As suggested by one government delegate, the trajectory of the process meant that: “None of the countries intended for certain things to be called dietary fibre, but because of the way the terminology was used you end up with an unintended consequence.” (Interview, February 2008). This admission suggests that the Codex methodology, rather than acting to enable discussion over the components of dietary fibre, was oriented towards the closure of negotiations. The operation of the methodology towards this goal meant that, once scientific terms had been used in a certain way – as a result of ‘defining’ – then those terms acquired a particular meaning which could not be easily questioned.

The boundary objects concept has been criticised for underemphasising the levels of difference between groups involved in the interpretation of the artefact (Gomart and Hennion, 1999). In the case of dietary fibre, it is due to precise disagreements that the boundary object has to be formed. More specifically, it is the scientific basis upon which standard-setting has to proceed which presents a problem for those trying to agree a definition, as scientific evidence cannot resolve the debate. Therefore, while specific scientific terms are used, the consequences of their use, and the lack of consensus over their meaning, result in the production of dietary fibre as a boundary object.

## 7.4 International Food Standards and Agri-Food Governance

The international food standards produced within the Codex system emerge through the application of a standard-setting methodology. As such, they are the product of a highly technical procedure which, in turn, produces governance instruments – standards – with considerable scientific and technical content. In order to ensure the agreement of a standard characterised by technical controversy it is likely that a boundary object will be produced to enable the finalisation of the process. Such agreement enables an international standard to be adopted by the Codex Commission, but does not necessarily resolve scientific or regulatory contention. In this situation, member governments of the Codex can utilise the relative ambiguity of the standard in making diverse regulatory interpretations.

As a particular mode of governance, Codex standard-setting corresponds to the deep risk regulation discussed by King and Narlikar (2003). Codex standard-setting occurs further upstream in the regulatory process than the production of knowledge claims, although as demonstrated in Chapters Four, Five and Six, these domains are highly interconnected. Conversely, the implementation of food standards occurs downstream from the Codex at the national and sub-national levels through the actions of enforcement officers, analysts and central government civil servants. Within this interchange, the Codex represents an international forum in which knowledge claims, national concerns and enforcement considerations are brought to bear upon the configuration of a standard. As such scientific facts and regulatory objects are created simultaneously. Latour (1987) suggests fact-builders (dealing with scientific activities) and object-builders (dealing with technical activities) construct objects capable of transmitting between different sites (termed immutable mobiles). In the case of dietary fibre, the distinction between fact-builder and object-builder collapses, with fact construction constituting the object, and the methodology for producing the object reliant upon the articulation of facts. Moreover, in order to accommodate the different interests involved in defining dietary fibre, dietary fibre had to become a boundary object. As discussed previously, there is a shared underlying premise behind the concepts of immutable mobiles and boundary objects. Both allow for the mediation of knowledge between different groups (or sites) through a common object, although the interpretations of this object may vary. Constructing such objects involves negotiation,



even when different groups retain their own interpretation. As a boundary object, dietary fibre has been constructed – through the act of defining in the Codex – in this way.

The standard-setting methodology is oriented around the construction of standards which will form international benchmarks for the development of national regulation. The strategic aim is to reduce difference between national regulatory systems – a harmonisation imperative – and therefore facilitate international trade with minimal conflict over the technical specifications or safety of food products. However, in focusing the standard-setting methodology upon resolution, an agreement can be produced which does not necessarily form a basis for regulatory harmonisation. Instead, boundary objects are produced which do not provide a final regulatory form and further assertions of knowledge claims are required. The production of boundary objects occurs as a result of contentious claims to knowledge being integrated within the Codex methodology. In this way, the standard-setting process responds to the articulation of authoritative knowledge claims, but such claims have to be asserted against other claims. As Rose (1993) suggests, the assertion of knowledge claims through recognised expertise is a defining characteristic of governance. The close relationship between knowledge claims, expertise and authority means that no single member government of the Codex can assert authority and, likewise, national forms of regulation respond, in part, to the formation of expert networks at the international level. One consequence of this is a cycle of regulatory science, which is initiated as controversy proves difficult to resolve. The conduct of regulatory science serves to galvanise groups of expertise and to further promulgate the controversy.

International food standard-setting is a highly technical process. Limited opportunities exist for diverse forms of expertise to influence the process, especially when dealing with a technical controversy. The problem of extension (Collins and Evans, 2002) applies to member governments of the Codex, not only to public interest groups. In this context the scientific basis of standard-setting cannot act as an arbiter of interests, but is instead an important element of controversy and contention. Resolving such issues is complex and context dependent. While the Codex process follows a methodology, the response of the process is specific to the standard in question. Primarily, the technical expertise in setting international food standards remains within the European (including,

in particular, the European Commission) and Cairns Group countries (and their associated systems of scientific advice providing the scientific expertise supported by knowledge claims). Although other member governments, such as Argentina, Brazil and India, are becoming more active in debates, technical expertise in the methodology of standard-setting remains the preserve of a relatively limited group. Expert groups initiated by the FAO/WHO can have an important influence upon the production of a standard – by possessing both scientific and technical expertise – but they cannot determine the final agreement. As the case of dietary fibre has demonstrated, a final agreement does not necessarily equate to the resolution of a controversy or to the production of unambiguous international standards.

The production of new or amended international food standards is of interest to food companies, as the development of regulation can provide new market opportunities. In particular, new standards can make possible forms of market differentiation which did not exist until the recognition of a standard. As suggested in the introduction to this chapter, in pressing for a wider definition for dietary fibre food companies anticipate new claims could be made for food products in development. Although food companies may be directly concerned with market differentiation, standards set norms and conventions and in doing so help to configure the behaviour of many actors involved in the governance of the agri-food system, as has been noted by Busch (2000). The implication is that the process of standard-setting is a negotiation over the scope for future action. In this sense standard-setting requires technical expertise not only to participate fully in the process, but also to anticipate how standard-setting may influence behaviour and conventions. In the case of dietary fibre, redefining the nutritional concept of dietary fibre to include food components previously considered to be outside the definition allows for the possibility to make new nutrition claims for food products. This not only means that products can be differentiated in the market, in addition new product ingredients can be produced which support the claims of food products to be ‘high in fibre’ or ‘a source of fibre’. From this perspective, technical governance devices such as methodologies can be considered as means by which companies can actively pursue the development of new standards in order to create new market conditions. The absence of a wider public involvement in the process means that controversial issues are dealt with as technical controversies, which are addressed using highly scientific and technical arguments and processes. The proliferation of

scientific evidence and advice within a technical process serves to increase contention over the issue. The process of setting international food standards is mediated by the standard-setting methodologies used within the Codex and by the nature of the controversy.

The depoliticisation of decision-making over international food standards is an outcome of political discussions being located within a highly scientific and technical institution as exemplified by the Codex. The rules of engagement (the methodology) and the constitution of the expertise required to engage in the process are important elements of this depoliticisation. Not only is the subject matter of the Codex process highly scientific and technical, but the technical methodology of the Codex has further reduced issues of governance to esoteric discussions of procedure and evidence. As discussed by Stanziani (2007), the agri-food sector has a history of producing regulation through negotiations conducted between competing interests. Such negotiations have always had a strong technical element, but are not *merely* technical discussions. Instead, in order for the governance of the agri-food system to have legitimacy, opportunities must exist for various interests to actively participate in the negotiation process. This requires greater recognition that establishing food regulation is politico-technical negotiation open to divergent understandings.

The aim of this thesis has been to contribute to the on-going analysis of the governance of the agri-food system at the international level through an examination of a particular mode of agri-food governance: international food standard-setting. In considering the governance of the agri-food system, Marsden (2000) has proposed that studies of agri-food governance should consider the highly differentiated co-ordination of individual and institutional actors operating in the governance of the agri-food system. The focus in this study has been upon the interactions of such actors within a specific institutional domain. International food standard-setting within the Codex is a distinctive form of agri-food governance and detailed analysis requires sustained engagement with particular instances of standard-setting. In particular the mobilisation of knowledge claims within the process has a profound influence upon the outcomes. Contestation over knowledge claims permeates the process and cannot be divorced from the negotiation of standards within policy-making environments. As suggested previously, the contribution of the epistemic communities concept to the analysis of international

food standard-setting – as a mode of agri-food governance – is restricted due to a failure to address the constitution of knowledge claims. In order to pursue an analysis of international food standard-setting it is necessary to conceptualise the production of scientific advice as an interactive process of the mobilisation of knowledge claims.

The above argument implies that studies of agri-food governance should conceptualise scientific and technical expertise as active elements in the attempt to assert authority. Accounts of agri-food governance which fail to address such factors can be criticised for omitting from analysis key areas of activity dealing with the materiality of the agri-food system. As suggested in Chapter Two, political economy accounts of the agri-food system often fail to incorporate the mobilisations of, and contestation over, knowledge claims. Such omissions generate analyses which do not recognise the active role of expertise in the governance of the agri-food system. Further work is required to understand how expertise is constituted and the role it has in guiding instruments of governance such as international food standards.

## Chapter Eight – Conclusions and Future Research

### 8.1 Conclusions

This thesis has analysed the process by which international food standards are set, focusing upon a case-study of the definition of dietary fibre. As detailed in Chapter One, two aims of the research were to produce a sociological analysis of the standard-setting process within the Codex Alimentarius Commission (the Codex) and to explore the broader implications of this analysis for understanding agri-food governance. In addition, the thesis aimed to draw conclusions about the operation of the Codex and to discuss future research questions and agendas. In particular, the study aimed to provide novel insights into the process of setting international food standards and, in doing so, to illuminate aspects of agri-food governance which frequently escape the attention of social scientists.

As argued in Chapter Two, traditional approaches to the political economy of the agri-food system have not been oriented towards investigating the role of scientific and technical knowledge in (to use a regulation school concept) the mode of regulation. Such short-comings have been addressed directly by governance perspectives on the agri-food system, which conceptualise expertise and expert networks as important actors. Debates over the governance of the agri-food system have drawn upon literatures which recognise the mobilisation of expertise as a core element in regulation, and regulation as an important steer within governance. Although such approaches have recognised the importance of understanding the techniques and practices of governing (Higgins and Lawrence, 2005), the role of scientific and technical expertise within agri-food governance remains underdeveloped. Governance approaches to the agri-food system have only infrequently subjected the production and mobilisation of knowledge claims to sustained analysis.

In assembling a framework to interpret international standard-setting, this thesis has considered the concept of epistemic communities. Expert networks have been recognised by some international relations scholars as having a significant impact upon the establishment of international agreements. From this perspective, it is proposed the

concept of epistemic communities provides a means of understanding how expert networks are formed and how they can influence international policy. While the concept of epistemic communities draws attention to the role of expertise in setting international policy-making, it can be criticised for employing an underdeveloped approach to the production and articulation of scientific and technical knowledge. This thesis concurs with such a critique by demonstrating how knowledge claims are active elements of the standard-setting process.

In this respect, work within science and technology studies (STS) suggests that the use of science within policy-making does not occur through an internally settled science providing inputs which are subsequently utilised by policy-makers. Instead, scientific and technical knowledge is a constituent of the policy-making process. The implications of STS approaches to the understanding of science and regulation were explored using a case-study of a particular instance of standard-setting within the Codex. In order to provide an in-depth, contextualised understanding of the process, the analysis focused upon a case-study of the agreement of a definition for dietary fibre in the Codex Nutrition Committee. As suggested in Chapter Three, using a case-study approach required that the case-study be produced by paying close attention to the operation of the Codex. Only through scoping activities – such as exploratory interviews with member government delegates and observations at the Codex Commission meeting – could the study become focused. The implication for studies of the standard-setting process in complex organisations such as the Codex is that a period of research scoping is necessary to become familiar with emerging issues.

The analysis of the case-study was divided into three Chapters. Chapter Four dealt with the negotiation of the definition for dietary fibre in the Nutrition Committee, while Chapter Five provided an analysis of the history of dietary fibre science and technology. Chapter Six focused upon the role of knowledge claims and scientific advice in the production of a Codex standard. Cumulatively the Chapters provide an analytical synthesis of empirical material generated from interviews, observations, documents and discussions with relevant actors. In this analysis it was apparent that science was not produced within an internally settled domain. Instead, tensions between scientists over the definition and analysis of dietary fibre became important elements of disagreement in regulatory spheres. Although scientific controversy over dietary fibre steadily built

from the late 1970s onwards, such contention emerged in conjunction with attempts to establish a European Community definition of dietary fibre. Within the Codex process, further disagreement over the knowledge claims was evident in a context of spiralling regulatory scientific activity. As a consequence, discussions became protracted and seemed unlikely to result in a consensual agreement.

Despite the unfavourable outlook for agreeing an international definition for dietary fibre in the Codex, in July 2009 a definition was adopted by the Codex Commission. As argued in Chapter Seven, agreeing a definition for dietary fibre involved acts of defining, conducted within a standard-setting methodology. The Codex methodology for standard-setting had to respond to diverse – and contentious – forms of scientific advice. In doing so, the methodology had to ensure that an agreement could be reached, in order to complete the task of producing a definition. In order to achieve this aim – through the act of defining – dietary fibre became a boundary object. As a boundary object, dietary fibre was defined with enough ambiguity to satisfy divergent knowledge claims, but also possessed enough coherency to remain identifiable as a distinct nutritional category.

An implication of the production of dietary fibre as a boundary object (as a consequence of the negotiations) is that while an international agreement was reached, this does not mean that contention over knowledge claims has been settled. Moreover, conceptualising dietary fibre as a boundary object means that divergent interpretations are not closed down. A single, limited definition of dietary fibre has not been produced. In addition, member governments remain able to interpret elements of the definition as they deem appropriate, as stated within the Codex standard. The implication is that while Codex standards are not mandatory – and so cannot be imposed upon member governments – a uniform (quasi-voluntary) agreement could not be reached.

The case-study of dietary fibre provided an empirical account of the Codex standard-setting process. The aim of the thesis was to examine Codex standard-setting as a mode of agri-food governance through a case-study approach. As suggested in Chapter Three, such an approach was expected to produce contextual understandings of the standard-setting process. In a broad sense, the thesis was concerned with addressing the question *'how are international food standards set?'* (see Chapter One). One response

to this question is to assert that international food standards are set using a methodology. How this methodology is applied may vary depending upon the issue under discussion, but the overriding aim of the methodology is to conclude the standard-setting process. Within the methodology, particular devices – such as defining – are used to narrow the scope for debate. A narrow scope for debate is essential if a standard is to be agreed and work completed. In order to contribute to this debate, participants must possess enough technical expertise to participate in the standard-setting methodology. Here, a ‘problem of extension’ (Collins and Evans, 2002) is apparent in that levels of technical expertise vary between member governments. From an STS perspective, standard-setting in the Codex exhibits technological properties due to the reliance on a methodology to ensure the success of the process. Not only is scientific expertise distributed unevenly between member governments (and this dependent upon overall levels of scientific expertise and scientific expertise relevant to the issue in question), but technical expertise is also required in order to participate in the methodology.

The process of setting international food standards also responds to any scientific contention or controversy which may exist over a particular standard. In Chapter Seven it was suggested that technical controversies pose distinctive problems of the standard-setting process. When international food standard-setting addresses a technical controversy, elements of the standard may become boundary objects in order to facilitate debate and enable a final agreement. Technical controversies – those controversies characterised by scientific contention but little public interest – are well suited to resolution through such methods. In part, this is due to the form contention over knowledge claims takes in the absence of wider public involvement. Scientific advice alone cannot provide the means by which agreement is reached. Moreover, a proliferation of scientific advice suggests that the scientific evidence base responds to activity in the standard-setting domain.

A more specific question was posed in Chapter One: ‘*are international food standards set on the basis of science?*’ This question asks whether the Codex conforms to the stated organisational objective of setting international food standards on the basis of science. In response, it can be asserted that while science is used in the production of a standard, the standard-setting process does not necessarily proceed on the basis of



science. To conceptualise standard-setting in this way is to misconstrue the standard-setting process and presumes that a scientific basis exists. Science is used in the standard-setting process but does not form a *basis* for negotiation. Where science is regarded as occupying a distinctive realm, boundary work is used rhetorically to support the division between scientific activity and standard-setting.

The scientific basis of standard-setting is further complicated by the prevalence of trans-scientific issues. The act of defining dietary fibre followed a methodology which aimed to resolve the standard-setting process, not to resolve the scientific debate over dietary fibre. Justifying the new classification of a nutritional category proved to be difficult, particular due to the scientific advice of the FAO/WHO. In attempting to agree a definition for dietary fibre, it was not possible to provide conclusive evidence in support of one particular definition in distinction from another. Debate over appropriate methods of analysis could not provide an answer to these questions, and discussions over this aspect of the controversy had to be left for future discussions. The scientific basis upon which components other than intrinsic non-starch polysaccharides ought to be included was not unchallenged and the standard-setting process for dietary fibre thus encapsulated a trans-scientific question while also being a technical controversy. As a result, a tension existed between scientific conceptualisations of the problem and a weakly articulated public health concern (relative to more public agri-food controversies – see Chapter Seven).

Within the standard-setting process, scientific advice is mobilised from diverse sources. The role of scientific advice in standard-setting was a direct concern of the thesis, with the following question posed: ‘*what is the relationship between scientific advice and standard-setting?*’ As demonstrated in Chapter Six, scientific advice is rooted in the production and articulation of knowledge claims. Even though the FAO/WHO claimed primacy in the provision of scientific advice to Codex Committees, competition between knowledge claims was evident. Knowledge claims did not exist in a separate domain to the standard-setting process, but were a component of the process. In this sense, scientific advice did not emerge from an autonomous domain. Instead, knowledge claims over dietary fibre proliferated even when conclusive proofs could not be obtained and used as a basis for action. Scientific advice becomes contested in such a situation and can be a consequence of the Codex methodology. As a draft standard is

advanced, a path-dependency serves to undermine the acceptance of new knowledge claims, especially those which contradict the draft standard. Recognising new knowledge claims can involve re-opening previous discussions, an action the Codex methodology is designed to avoid.

The difficulty in establishing a scientific basis for standard-setting is not only a result of competing knowledge claims, as the organisation of the relationship between scientific advice and standard-setting influences the process. In this respect the thesis sought to answer the question: *‘how does the institutional organisation of standard-setting influence the standard-setting process?’*. As detailed in Chapter Three, the operation of the Codex is governed by a complex organisational structure, involving numerous committees and several important procedural conditions. Despite the prescriptions of the risk analysis framework in separating the activities of risk assessment (scientific advice) and risk management (standard-setting), in the case of agreeing a definition for dietary fibre the division between risk assessment and risk management was deemed to be largely a rhetorical one. Of greater significance was the maintenance of the standard-setting process through the application of a methodology. Contention over knowledge claims could easily have undermined the standard-setting process if a strict division existed between risk assessment and risk management, particularly if standards were set on the basis of science. Instead, scientific controversy was negotiated as an element of the standard-setting process, following the procedure for elaborating Code standards.

Given the Codex standard-setting process aims to produce consensus between member governments over the final standard, the thesis also attempted to explain *‘how is consensus established amongst member governments in order to agree international food standards?’* In the case of a protracted and technically controversial standard such as the definition of dietary fibre, the standard-setting process is not characterised by widespread consensus. Despite this an agreement was achieved. The trajectory of the Codex methodology upon completing the work of standard-setting had a major impact upon the successful establishment of the definition. By negotiating dietary fibre as a boundary object, interested parties could each retain their own interpretation. As a result a consensus on the definition could be achieved given that – as a boundary object – dietary fibre could be conceptualised in multiple ways. The production of a boundary

object within standard-setting means that the process can be completed on the basis of consensus without directly settling the controversy.

The negotiation of dietary fibre as a boundary object emerged from competing knowledge claims. These claims differed in their conception of what constituted dietary fibre and how these materials could be analysed and measured. As such, this finding addressed the question *‘how are the material components of food products conceptualised within the standard-setting process?’* The chemical and biological properties of dietary fibre were core issues of debate within the standard-setting process. However, by producing dietary fibre as a boundary object, the agreed definition avoided providing a strict demarcation of the material components of dietary fibre. In this way, the properties of dietary fibre became items of discussion. At the same time, these properties imposed particular constraints upon methods for analysis and measurement of dietary fibre. Dealing with the measurement and analysis of dietary fibre proved too complex a debate within the establishment of a definition for dietary fibre and this discussion was reserved for a future session of the Codex Nutrition Committee.

The final question posed in Chapter One asked *‘what are the implications of this analysis of international food standard-setting for understanding the governance of the agri-food system?’* This is a wide-ranging question which deals with issues raised in Chapter Two – in particular approaches to analysing the governance of the agri-food system – and developed throughout the thesis. As suggested previously, standard-setting is a highly technical form of policy-making involving a methodology. By proceeding on the basis of a methodology, international standard-setting – a potentially fractious activity – maintains a stability and coherency. As a particular mode of agri-food governance, international food standard-setting not only has a distinctive process for policy-making, but also illuminates similarities and differences in the ways that member governments of the Codex produce knowledge claims and engage with international negotiations. Moreover, by focusing analysis upon the production and articulation of knowledge claims, the interrelationship of national and international forms of expertise can be revealed.

Conducting the research and analysis summarised above proved extremely challenging. As suggested, the issues comprising international food standard-setting are scientifically

and technically complex. This complexity has implications not only for the process of setting standards, but also for studying and analysing the standard-setting process. Becoming competent in the scientific and technical discussions is a requirement for such a study. However, developing competency in scientific and technical matters is an outcome of interactions with those participating in the standard-setting process, whether, regulators, scientists or other actors. Therefore, carrying out empirical research is a requirement not only for the development of analytical understanding, but also for the immersion of the researcher into the field of inquiry.

The difficulties associated with understanding scientific and technical negotiations are compounded by the international context of standard-setting in the Codex, in two main ways. Firstly, dealing with diverse actors, from different regulatory cultures and with particular conceptualisations of the issue under discussion requires considerable patience. Being granted the time to carry out interviews and discuss issues with these actors is a slow and delicate process. Frequently, it may not be possible to arrange an interview with an important actor and this must be accepted. Secondly, those most closely involved in an issue subject to standard-setting are distributed across the globe. As discussed in Chapter Three, considerable resource constraints existed for the study and it was not possible to pursue every dimension, even if relevant. Due to the diversity and varied locations of the relevant actors – combined with costs associated with attending Codex meetings – some elements of the standard-setting process for dietary fibre require further study. In this respect there is considerable scope for future research, not only on the case-study produced in this thesis, but in contextualising this account through a comparative approach and in broadening the scope of the research. These issues will be discussed in the following section.

## 8.2 Future Research

In focusing upon the process of international food standard-setting in the Codex, using a single in-depth case-study, this thesis has inevitably produced more questions than could be answered. Perhaps the most obvious question to emerge from the study is to ask how the process for defining dietary fibre in the Codex compares to other processes within the Codex system. As suggested in Chapter Three, an in-depth comparative

study of two or more standards was considered in the research design, but became impossible to implement given resource and time constraints. Additional cases could have been incorporated into the study, but this may result in a less rigorous analysis. A more satisfactory development would be the extension of research design and execution discussed in this thesis to incorporate the production of additional standards. Comparative studies would be possible of the standard-setting process for other standards within the same Codex Committee (e.g. two or more standards within the Codex Nutrition Committee). Alternatively, standard-setting in different committees could be compared. Further, different types of Codex standards could be compared. For instance, cases of technical controversies (of the type characterising the definition of dietary fibre) could be identified and compared. Of course, it is possible that what may seem to be technical controversies could eventually be conceptualised as a different kind of controversy. Regardless, all the comparative designs mentioned above would provide new insights into the process and would also provide new means of understanding the case-study which has been presented in this thesis.

A further development of this study would be to follow the standard-setting process in one of two directions: upstream (towards the production of knowledge claims) and downstream (towards the implementation of national regulations subject to international standards). Of course, the distinction between upstream and downstream is not strict (as has been demonstrated in this thesis). However, the study placed the standard-setting process at the centre of analysis and worked outwards into other institutional domains in order to explain the negotiation process. Alternative approaches may seek to build upon these findings by exploring in greater detail how national regulation has been impacted by a standard agreed at the international level. Similarly, further work could be carried out to understand how knowledge claims have been produced. This would involve concentrating upon the activities of scientists within their places of work. Such a focus would be particularly interesting in the context of on-going standard-setting processes and would provide an understanding of the relationship between the conduct of science and the conduct of policy.

Developing comparative, upstream and downstream approaches to the sociological analysis of international trade regulation is a pressing requirement. Sustained application of insights from science and technology studies (STS) to the governance of

the agri-food sector remains limited at present. In addition, understanding the consequences of intergovernmental processes for the regulation of the emergent agri-food system requires attention to other forms of standard-setting and auditing (Busch and Bain, 2004). While this thesis has contributed significantly to the development of a more sustained application of STS approaches to the sociological analysis of the agri-food system, further work is required in this respect. The interplay of science, technology and regulation is a critically important steer upon the trajectory of the food sector, at many levels of analysis.

An important contribution to future studies of the governance of the agri-food system could be made by interdisciplinary approaches, involving both natural and social scientists. In this thesis, scientists played an active part not only as interviewees but also as respondents and discussants over written text. However, inviting natural scientists to become research partners in the study of agri-food governance allows for exciting opportunities for a more active sociological analysis. This form of analysis would not only seek to interpret, analyse and document, but take a more pro-active role in the production of science alongside considerations of social implications. The study of international food standard-setting presented here demonstrates that scientific activity has an important role to play not only in the laboratory and field, but also in the construction of the world. This construction occurs inside and outside of formal political processes and demands the attention of social scientists.

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The completion of this consent form permits the use of material in a doctoral research project being undertaken by Richard Lee, Newcastle University, UK.

It confirms that I \_\_\_\_\_ have granted permission for Richard Lee to use the interview material produced during our discussions subject to the following conditions:

- all data produced will be fully confidential.
- approval will be sought from the interviewee before material is used.
- the use of direct quotations will be subject to approval by the interviewee.

Additional conditions:

Signature:

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## Appendix II

### Interviews conducted:

- 1) 18<sup>th</sup> May 2007 Interview with government civil servant / Codex delegate
- 2) 14<sup>th</sup> June 2007 Interviews conducted with participants of UK National Codex Contact Meeting
- 3) 3<sup>rd</sup> July 2007 Interview with government civil servant / Codex delegate
- 4) 5<sup>th</sup> July 2007 Interview with a group of government delegates to Codex Commission
- 5) 16<sup>th</sup> July 2007 Interview with government civil servant / Codex delegate
- 6) 16<sup>th</sup> July 2007 Interview with consumer group representative
- 7) 13<sup>th</sup> August 2007 Interview with academic
- 8) 13<sup>th</sup> August 2007 Interview with academic
- 9) 11<sup>th</sup> October 2007 Interview with Codex risk assessor
- 10) 24<sup>th</sup> October 2007 Interview with government civil servant / Codex delegate
- 11) 11<sup>th</sup> November 2007 Interview with ILSI representative
- 12) 12<sup>th</sup> November 2007 Interview with industry representative
- 13) 12<sup>th</sup> November 2007 Interview with industry representative
- 14) 15<sup>th</sup> November 2007 Interview with government civil servant / Codex delegate
- 15) 15<sup>th</sup> November 2007 Interview with government civil servant / Codex delegate
- 16) 15<sup>th</sup> November 2007 Interview with government civil servant / Codex delegate
- 17) 12<sup>th</sup> February 2008 Interview with government civil servant / Codex delegate
- 18) 18<sup>th</sup> February 2008 Interview with government civil servant / Codex delegate
- 19) 18<sup>th</sup> February 2008 Interview with government civil servant / Codex delegate
- 20) 26<sup>th</sup> February 2008 Interview with scientist
- 21) 3<sup>rd</sup> April 2008 Interview with government civil servant / Codex delegate
- 22) 7<sup>th</sup> April 2008 Interview with scientist
- 23) 20<sup>th</sup> May Interview with government civil servant / Codex delegate
- 24) 23<sup>rd</sup> July 2008 Interview with scientist
- 25) 23<sup>rd</sup> July 2008 Interview with scientist
- 26) 19<sup>th</sup> August 2008 Interview with government civil servant / Codex delegate
- 27) 19<sup>th</sup> August 2008 Interview with scientist
- 28) 1<sup>st</sup> December 2008 Interview with scientist
- 29) 2<sup>nd</sup> December 2008 Interview with scientist
- 30) 3<sup>rd</sup> December 2008 Interview with scientist
- 31) 7<sup>th</sup> January 2009 Interview with ILSI representative
- 32) 18<sup>th</sup> February 2009 Interview with industry representative